

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2014
OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____
Commission File Number 001-36200

OXFORD IMMUNOTEC GLOBAL PLC

(Exact name of registrant as specified in its charter)

England and Wales
(State or Other Jurisdiction of
Incorporation or Organization)

98-1133710
(I.R.S. Employer
Identification No.)

94C Innovation Drive, Milton Park, Abingdon OX14 4RZ, United
Kingdom
(Address of Principal Executive Offices)

Not Applicable
(Zip Code)

+44 (0)1235 442780
(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of each class</u>	<u>Name of exchange on which registered</u>
Ordinary Shares, £0.006705 nominal value per share	The NASDAQ Global Market

Securities registered pursuant to Section 12(g) of the Act
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes No

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports); and (2) has been subject to such filing requirements for the past 90 days. Yes No

[Table Of Contents](#)

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act (check one):

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company
(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of March 2, 2015, there were 22,509,772 Ordinary Shares, nominal value £0.006705, of Oxford Immunotec Global PLC outstanding.

As of June 30, 2014, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the registrant's Ordinary Shares held by non-affiliates was approximately \$242,342,945.

DOCUMENTS INCORPORATED BY REFERENCE

The following documents (or parts thereof) are incorporated by reference into the following parts of this Form 10-K: Certain information required by Part III of this Annual Report on Form 10-K is incorporated from our definitive proxy statement pursuant to Regulation 14A, to be filed with the Commission not later than 120 days after the close of our fiscal year ended December 31, 2014.

Special Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K, and exhibits hereto, contains or incorporates by reference estimates, predictions, opinions, projections and other statements that may be interpreted as “forward-looking statements” within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). The forward-looking statements are contained principally in Part I, Item 1: “Business,” Part I, Item 1A: “Risk Factors,” and Part II, Item 7: “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” but are also contained elsewhere in this Annual Report. In some cases, you can identify forward-looking statements by the words “may,” “might,” “will,” “would,” “could,” “should,” “intend,” “plan,” “contemplate,” “expect,” “anticipate,” “believe,” “estimate,” “predict,” “project,” “target,” “potential,” “continue,” and “ongoing” and other comparable expressions intended to identify statements about the future, although not all forward-looking statements contain these identifying words. These statements involve substantial known and unknown risks, uncertainties and other factors that may cause our actual results, level of activity, performance or achievements to differ materially from those currently anticipated. Forward-looking statements are neither historical facts nor assurances of future performance. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Annual Report, we caution you that these statements are based on a combination of facts and factors currently known by us and our expectations of the future, about which we cannot be certain and that involve substantial risks and uncertainties. Such risks and uncertainties include, but are not limited to:

- our history of losses, our ability to achieve or sustain profitability and our ability to manage our growth;
- our ability to further develop, commercialize and achieve market acceptance of our current and future products;
- our ability to successfully develop and complete the acquired in process research and development, or IPR&D, program and profitably commercialize the underlying product candidates before our competitors develop and commercialize similar products, or at all;
- continued demand for diagnostic products for tuberculosis and the development of new market opportunities;
- our ability to compete successfully and to maintain and expand our sales network;
- decisions by insurers and other third party payors with respect to coverage and reimbursements;
- our dependence on certain of our customers, suppliers and service providers;
- disruptions to our business, including disruptions at our laboratories and manufacturing facilities;
- our ability to effectively use our current financial resources and our ability to obtain additional capital resources;
- the integrity and uninterrupted operation of our information technology and storage systems;
- the impact of currency fluctuations on our business;
- our ability to make successful acquisitions or investments and to manage the integration of such acquisitions or investments;
- our ability to retain key members of our management;
- the impact of taxes on our business, including our ability to use net operating losses;
- the impact of legislative and regulatory developments, including healthcare reform, on our business;
- the impact of product liability, intellectual property and commercial litigation on our business;
- our ability to comply with SEC reporting, antifraud, anti-corruption, environmental, health and safety laws and regulations;
- our ability to maintain our license to sell our products around the world, including in countries such as China;
- our ability to protect and enforce our intellectual property rights;
- our status as an emerging growth company and as an English company listing ordinary shares in the United States;
- the volatility of the price of our share price, substantial future sales of our shares and the fact that we do not pay dividends; and
- the impact of anti-takeover provisions under U.K. law and our articles of association.

You should refer to “Item 1A, Risk Factors” in this Annual Report for a discussion of other important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Annual Report will prove to be accurate. Further, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us that we will achieve our objectives and plans in any specified time frame, or at all. The forward-looking statements in this Annual Report represent our views only as of the date of this Annual Report. Subsequent events and developments may cause our views to change. While we may elect to update these forward-looking statements at some point in the future, we undertake no obligation to publicly update any forward-looking statements, except as required by law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Annual Report.

Table of Contents

	<u>Page</u>
<u>PART I</u>	
Item 1. Business	1
Item 1A. Risk Factors	24
Item 1B. Unresolved Staff Comments	43
Item 2. Properties	43
Item 3. Legal Proceedings	43
Item 4. Mine Safety Disclosures	43
<u>PART II</u>	
Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	44
Item 6. Selected Consolidated Financial Data	47
Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations	50
Item 7A. Quantitative and Qualitative Disclosures About Market Risk	66
Item 8. Financial Statements and Supplementary Data	67
Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	68
Item 9A. Controls and Procedures	68
Item 9B. Other Information	68
<u>PART III</u>	
Item 10. Directors, Executive Officers and Corporate Governance	69
Item 11. Executive Compensation	69
Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	69
Item 13. Certain Relationships and Related Transactions, and Director Independence	69
Item 14. Principal Accounting Fees and Services	69
<u>PART IV</u>	
Item 15. Exhibits, Financial Statement Schedules	70
Signatures	75

Part I

Item 1. Business

Overview

We are a global, commercial-stage diagnostics company focused on developing and commercializing proprietary tests for the management of immune-regulated conditions. Our proprietary T-SPOT^{®1} technology platform allows us to measure the responses of specific immune cells to inform the diagnosis, prognosis and monitoring of patients with immune-regulated conditions. Our current development activities are principally focused on four areas: chronic infections, transplantation, autoimmune and inflammatory disease and immune-oncology. We believe these areas are particularly attractive for the development of diagnostic tests because they involve large patient populations and chronic conditions that present the opportunity for both initial diagnosis and additional testing to monitor the conditions. These immune-regulated conditions also tend to be characterized by wide variation in presentation and progression and often require expensive therapies, making diagnostic tests that can better categorize patients and inform treatment pathways particularly useful. We believe the sensitivity of our T-SPOT technology platform, which can measure T cell and innate immune cell responses at a single cell level well position us to bring new insights into the diagnosis, prognosis and monitoring of immune-regulated conditions.

The initial product we have developed using our T-SPOT technology platform is our T-SPOT.*TB* test, which is used to test for Tuberculosis (TB) infection. Our T-SPOT.*TB* test has been approved for sale in over 50 countries, including the United States, where we have received pre-market approval, or PMA, from the Food and Drug Administration, or FDA, in Europe, where we have obtained a CE mark, as well as in Japan and China. Our T-SPOT.*TB* test has been included in clinical guidelines for TB screening in at least 17 countries, including the United States, several European countries and Japan. In addition, we have established reimbursement for our test in the United States, as well as a Current Procedural Terminology, or CPT², code that is unique to our test. Outside the United States, we have established reimbursement in several countries where reimbursement applies, including Japan, Switzerland and Germany. We have also established the cost-effectiveness of our test in several published studies.

We have seven active development programs pertaining to new potential tests. Each program seeks to exploit our T cell or innate immune measuring technology, and these programs cover each of our four focus areas.

Our most advanced product in development leverages our T-SPOT technology platform to assess the strength of a patient's cellular immune response to cytomegalovirus, or CMV, infection, assisting clinicians with monitoring anti-viral prophylaxis and evaluating patients at risk from CMV disease. We expect to complete development of our T-SPOT.*CMV* assay as a laboratory developed test, or LDT, in the United States, and to CE mark the test in Europe, in the first half of 2015. We are currently conducting two pivotal clinical studies to provide the evidence needed to drive adoption and acceptance by the medical and payor communities of this test. We expect to have the results of these studies in 2016.

Our second product in development is our T-SPOT.*PRT* (Panel of Reactive T-cells) test. This test, also based on our T-SPOT technology platform, assesses T cell responses to foreign tissue as a means of better informing organ rejection risk in current or potential transplant recipients. We expect to complete development of our T-SPOT.*PRT* assay as an LDT in the United States, and to CE mark the test in Europe, in the second half of 2015. We are currently conducting a pivotal clinical study to provide the evidence needed to drive adoption and acceptance by the medical and payor communities of this test. We expect to have the results of this study in 2017.

Our development pipeline also includes an assay to assess the overall competence of a transplant patient's immune system, products targeting autoimmune and inflammatory diseases, such as gout and Lyme disease, as well as informing the efficacy of biologic therapies; and a program to explore applications of our T-SPOT technology platform in the immune-oncology space. These products are in earlier stages of development.

We believe the annual global market opportunity for our T-SPOT.*TB* test is well in excess of \$1 billion, assuming we can largely displace the Tuberculin skin test, or TST, in the developed world. We believe the global market opportunity for our products directed to transplantation and autoimmune-inflammatory disease to be in excess of \$2 billion, although our market sizing estimates remain preliminary. We have not yet sized the market opportunity for our technology in immune-oncology given the early stage of this program.

¹ "T-SPOT[®]," "T-Cell *Xtend*[®]," "Oxford Diagnostic Laboratories[®]," "ODL[®]," "SpiroFind[®]," the Oxford Immunotec logo, our laboratory logo and other marks are our trademarks. Solely for convenience, trademarks and trade names referred to in this Annual Report on Form 10-K, including logos, artwork and other visual displays, may appear without the [®] or [™] symbols, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights to these trademarks and trade names.

² CPT is a registered trademark of the American Medical Association.

[Table Of Contents](#)

We are a global business with 240 employees, including sales and marketing teams on three continents, and laboratories in the United States and the United Kingdom. In 2014, we sold to customers in over 50 countries and derived 54% of our revenue from outside the United States. Our current customer base includes more than 1,100 active customers, consisting of hospitals, public health departments, commercial testing laboratories, importers and distributors.

Tuberculosis

Tuberculosis is a common and, if not properly treated, potentially lethal infectious disease caused by a bacterium called *Mycobacterium tuberculosis*. When an individual with active TB disease of the respiratory tract coughs, sneezes, yells or spits, respiratory fluid droplets that contain *M. tuberculosis* are expelled into the air and can infect others. TB typically infects the lungs, but the lymph nodes, kidneys, brain and bones may also be infected. Within two to ten weeks of the original infection, a specific T cell immune response usually develops. This immune response prevents further multiplication and spread of the TB bacteria. Individuals who have a successful T cell immune response will still have live bacteria in their body and are considered to have latent Tuberculosis infection, or LTBI. Those with LTBI are asymptomatic and are not infectious; however, each person with LTBI has a 10% chance, on average, of progressing to active TB disease over his or her lifetime.

TB is considered to have progressed to active TB disease when the body is unable to effectively control the replication of the TB bacteria and their growth causes damage to the body. This risk of progression to active TB disease is significantly elevated among individuals with weakened immune systems, such as smokers, those with human immunodeficiency virus, or HIV, or diabetes or those on drugs that suppress the immune system (e.g., those taking biologic therapies for autoimmune disease or those undergoing immune suppression post-transplantation). When a person develops active TB disease, the symptoms, including coughing, chest pains, weakness, weight loss, fever and night sweats, may be mild for many months. This can lead to delays in seeking care, which can result in transmission of the bacteria to others. As the disease progresses, the person may develop symptoms that can become increasingly worse. Without proper treatment, up to two thirds of people with active TB disease will die.

According to the World Health Organization, or WHO, approximately one-third of the world's population, over two billion people, is infected with *M. tuberculosis*. This represents an enormous population of infected persons at risk of progressing to active TB disease. Despite the availability of an effective treatment, TB is one of the leading causes of infectious disease death worldwide. In 2013, the WHO estimated that approximately 9.0 million people contracted active TB disease, of which approximately 1.5 million people died. TB is a leading killer of people living with HIV, causing one quarter of all deaths in that population. Although TB rates are declining slowly across the world, even in the developed world, current screening and management tools have failed to eliminate the disease. For example, in the United States an estimated 11 million people have LTBI, which acts as a constant source of new infections. In addition, new cases of TB commonly arise from immigration and from travel to and from countries with higher incidence of TB.

There are three broad strategies to control TB: vaccination, finding and treating active TB disease, and finding and treating LTBI to prevent the development of new cases.

- *Vaccination.* The traditional means of seeking to protect individuals who may be exposed to infectious diseases is vaccination. The only vaccine available for TB is the Bacille Calmette-Guerin, or BCG, vaccine, which was first used in the 1920s. The vaccine is widely used around the world outside the United States; however, BCG's efficacy is highly variable and it does not provide adequate protection against TB disease in adults. Therefore, the vaccine alone is insufficient to control TB.
- *Finding and treating active TB disease.* Although TB is typically a curable disease when treated with the standard multi-month regimen of potent antibiotics, diagnosing active TB can be problematic. For instance, TB symptoms are often non-specific and/or confused with other diseases, causing delays in seeking and receiving appropriate medical diagnosis. In addition, traditional diagnostic tests for active TB disease are imperfect. Delays in diagnosis result in increased morbidity and mortality and worsen the spread of TB infection, as people with active TB disease can infect as many as 10 to 15 people per year. The emergence of drug-resistant TB strains is a growing problem, as they make treatment with standard anti-TB drugs more difficult and in some instances, where resistance is present to all front-line drugs, the mortality rate exceeds 50%.
- *Finding and treating LTBI.* The identification of individuals with LTBI by screening high-risk groups is an essential component of TB control in developed markets. In the United States, for example, screening high-risk groups has been an important practice for more than four decades. In the United States and other countries with a low incidence of TB, most new, active TB disease cases have occurred among persons who were once infected, contained the initial infection, and then later progressed from LTBI to active TB disease. The identification and treatment of individuals with LTBI prevents any further risk of these individuals progressing to active TB disease and prevents the further spread of TB.

The United States has one of the most comprehensive LTBI screening programs in the world. Several high-risk groups have been identified by the U.S. Centers for Disease Control and Prevention, or the CDC, for screening and subsequent treatment of LTBI, including:

- healthcare workers;
- those with immunosuppressive conditions, such as diabetes and certain carcinomas, persons receiving organ transplants and persons receiving immunosuppressive agents;

[Table Of Contents](#)

- those with HIV and those working at HIV clinics;
- refugees and immigrants from countries with high incidence of TB;
- close contacts of active TB cases;
- prisoners and jail detainees, as well as staff employed in prisons and jails;
- intravenous drug users and staff employed at substance abuse centers;
- homeless persons and staff employed at homeless facilities; and
- those living in congregate living facilities, such as nursing homes or assisted living facilities.

In addition to the screening of high-risk groups recommended by the CDC, TB screening is also mandated by many states to include additional populations, such as day care staff, school teachers and pupils, and police officer candidates. Additionally, the screening of healthcare workers is recommended as part of the accreditation standards for U.S. hospitals and screening of certain U.S. military personnel for LTBI is included in military guidelines.

Generally, other developed markets have similar practices to screen high-risk groups for LTBI, although the populations screened may differ from those in the United States.

In total, we estimate that there are 22 million LTBI tests performed each year in the United States, the majority of which are performed within the healthcare system in a variety of settings, including hospitals, public health offices, physicians' offices and clinics. Outside the United States, we estimate the total number of tests to be 28 million each year, for a combined market size of 50 million LTBI tests annually.

Current TB skin test and its limitations

The primary test currently used for TB screening is the 100-year-old TST. The TST is administered by injecting an extract from cultured *M. tuberculosis*, called Tuberculin or PPD, into the skin of a subject's forearm using a needle and syringe. The injection of the PPD into the skin of a subject previously infected with TB stimulates the immune response, including T cells, causing the formation of a hard lump at the site of the injection. Because it takes time for this reaction to occur, the subject must return 48 to 72 hours after the PPD injection to have the result read. The test result is graded by feeling for the boundaries of the swelling, marking these with a pen and then measuring the diameter with a ruler.

The TST suffers from several limitations, including the following:

- *Antiquated technique results in substantial test variability.* The technique of administering the PPD injection and reading the TST is inherently variable. Too little of the PPD may be injected to stimulate the appropriate response, the injection may be too shallow, allowing the PPD to leak out of the skin, or the PPD may be injected too deeply to stimulate the appropriate response. Because this technique is inherently operator dependent, healthcare workers who administer the PPD injections and read TST tests should undergo specialist training. However, even with such training, test results vary with the training levels, responsibility, and conscious and unconscious bias of the healthcare workers administering the injections and reading the tests. Variability in the size of the swelling due to administration of the injection averages approximately 15%. Similarly, variation in reading test results among experienced healthcare workers is also estimated at approximately 15%.
- *Multiple patient visits required.* The TST requires that the patient return 48 to 72 hours from the time of injection. This requirement presents a significant logistical challenge. Additionally, non-return rates can be as high as 30%, resulting in considerable time and money being wasted to persuade the subjects to be rescreened as well as the duplicated materials costs and time associated with retesting.
- *False negatives.* False-negative results to the TST are common due to a number of factors relating to the quality of the PPD used and the patient receiving the injection. Specifically, the PPD may be improperly stored, improperly diluted or contaminated. In addition, a fungal, viral or bacterial infection (including active TB disease) can suppress the TST response, leading to a false-negative. False negatives are also prominent among newborns and elderly subjects. Other conditions can also cause false-negative TST results, including HIV, certain live-virus vaccinations (e.g., measles, mumps and polio), chronic renal failure, nutritional factors, diseases affecting the lymphoid organs (e.g., Hodgkin's disease, lymphoma, chronic lymphocytic leukemia and sarcoidosis), drugs (e.g., corticosteroids, tumor necrosis factor (TNF) biologics and many other immunosuppressive agents) and stress.
- *False positives.* False-positive results to the TST are common and are attributed to the presence in the PPD of antigens that are shared with other mycobacteria. As a result, the TST can cross-react in those patients who are infected with non-tuberculous mycobacteria as well as those patients who have received the BCG vaccine, which is the most widely administered vaccine in the world.
- *"Boosting" of results.* The TST result can also be "boosted," which occurs when an infected subject's reaction to an initially false-negative skin test causes increased sensitivity in a subsequent test such that it tests positive. The misinterpretation of a boosted reaction as a new infection with *M. tuberculosis* can result in unnecessary additional testing for the subject, unnecessary treatment and unnecessary testing of other personnel. As a result of this "boosting" effect, when the TST is used, the CDC recommends two-step testing for newly employed healthcare workers in order to ensure that an initial negative test is not a false negative. This recommendation effectively requires four patient visits when using the TST (two administrations of the PPD and two reads), a process that can lead to significant and costly delays in the hiring of new personnel at U.S. healthcare institutions.

Our T-SPOT.*TB* solution

Our T-SPOT.*TB* test is a highly sensitive and specific, single-cell based method for identifying TB infection. It is a single-tube blood test that directly measures antigen-specific T cells that indicate TB infection.

Our T-SPOT.*TB* test takes advantage of the T cell response that results from infection with *M. tuberculosis*. Our T-SPOT.*TB* test quantifies individual *M. tuberculosis*-sensitized T cells by challenging them with *M. tuberculosis* antigens that are recognized by the immune system. We employ two antigens, ESAT-6 and CFP10, to stimulate T cells that have previously been exposed to *M. tuberculosis*, which causes them to release a cytokine called interferon-gamma. Interferon-gamma is one of the dominant cytokines released by activated T cells when encountering *M. tuberculosis*. In contrast to the PPD reagent used in the TST, these two antigens are not shared with the BCG vaccine or with non-tuberculous mycobacteria. Because our test detects individual T cells via their release of interferon-gamma, our test is sometimes referred to generically as an interferon-gamma release assay, or IGRA.

Under our flexible business model, we currently offer our T-SPOT.*TB* test in either an *in vitro* diagnostic kit or a service format. In the former, we sell test kits and associated accessories to laboratories for them to perform the testing themselves. In the latter, we have established clinical testing laboratories in the United States and the United Kingdom, where we perform our T-SPOT.*TB* test on samples sent to us by customers. In these markets, we have found that many customers prefer to send samples to us rather than perform their own analysis on-site. We market our service offering under the name Oxford Diagnostic Laboratories, or ODL.

Our ODL service is typically comprised of the following steps:

- The customer draws a blood sample and places it in a pre-paid, re-usable, specialized shipping container that we provide, along with a completed test requisition form.
- The sample is picked up by our designated courier (although customers can also drop off samples themselves to courier locations) and shipped overnight.
- When the package arrives at our ODL facilities, we unpack and enter the sample data into our laboratory information system, or LIS. The LIS assists us in sample processing and tracking and provides various automation options for result delivery and invoicing.
- We process the sample and, once the test is complete, we report the results back to the customer and submit an invoice to the customer or, in certain cases, to a patient's insurance provider. We have various mechanisms for customers to order and receive their results according to their preference, including fax, encrypted e-mail, web-portal or an interface with their electronic medical records system.

We have developed our next generation T-SPOT.*TB* test, which incorporates automation at every step of the test, and it is now validated for use in our Memphis ODL facility. Automation will make the test less costly to run at our own ODL facilities in Memphis, TN and Oxford, UK. Our kit customers may likewise benefit from this fully automated solution for their T-SPOT.*TB* test needs.

Although primarily designed for use in detecting LTBI, our test can also be used to assist in the diagnosis of active TB disease, particularly in suspected cases where conventional diagnostic methods such as chest x-ray or sputum smear are inconclusive. Because infection is a pre-requisite for disease, ruling out LTBI can aid physicians in diagnosing a different disease or condition. Our test has been included in guidelines in several countries for this purpose, such as those from the Netherlands, France, Ireland and Italy.

Our T-SPOT.*TB* strategy

Our objective is to increase adoption of our T-SPOT.*TB* test for screening and detecting persons infected with TB infection. To achieve this objective, our strategy is to:

- *Accelerate our penetration into proven market segments in the United States.* We intend to continue to invest in our direct sales and customer service teams to increase our capacity to cover the hospital and public health segments, which have primarily supported our success to date. In addition, we expect to continue building upon our marketing and medical education programs to increase awareness and understanding of the advantages of our T-SPOT.*TB* test over the TST, including by leveraging scientific publications, such as the SWITCH study results.
- *Expand into other market segments in the United States.* We intend to increase our presence in other market segments where feasible, including physicians' offices, universities, chronic care facilities and the military. We are building a direct sales team and investing in marketing activities targeting physicians' offices.
- *Expand our commercial presence outside the United States.* We intend to continue making investments to expand our sales presence and marketing teams, particularly in Europe and Japan. In 2014, we opened an office in Shanghai, China and intend to establish a presence in select additional geographies to accelerate test adoption in countries where we already have regulatory approval.
- *Expand our addressable market outside the United States.* We intend to continue to invest in opening up new markets by gaining additional regulatory approvals. In addition, we intend to continue to invest to develop markets in which we already have regulatory approval through generating the data to yield supportive guidelines and reimbursement.

Regulatory approvals and clinical validation

Our T-SPOT.*TB* test is approved for commercial sale in over 50 countries. Key geographies where we have regulatory approval include:

- *The United States*. We obtained PMA for our T-SPOT.*TB* test from the FDA in 2008. Since 2008, an additional ten PMA supplements have been approved, including supplements relating to manufacturing improvements and label extensions, such as those that enable overnight shipment of blood samples.
- *Europe*. We obtained a CE mark in 2004, which allows us to sell our T-SPOT.*TB* test in Europe as well as other countries that accept the CE mark.
- *China*. We obtained initial approval for our T-SPOT.*TB* test from the China Food and Drug Administration, or the CFDA, in 2010. Consistent with CFDA re-registration requirements, we secured re-registration of our test in 2014, which will remain effective until 2019.
- *Japan*. We obtained approval for our T-SPOT.*TB* test from the Ministry of Health, Labour and Welfare, or MHLW, in 2012.

Two key metrics measured by the regulatory bodies responsible for approving our T-SPOT.*TB* test are *sensitivity*, a measure of how many test positives there are in a population known to be infected, and *specificity*, a measure of how many test negatives there are in a population known to be uninfected. The following is a chart showing the performance of our T-SPOT.*TB* test in studies conducted in certain key geographies:

Country/Region (trial size)	Sensitivity (%)	Specificity (%)
United States (2,355 subjects)	95.6%	97.1%
Europe (180 subjects)	98.8%	100%
China (1,333 subjects)	95.3%	Not applicable*
Japan (212 subjects)	97.5%	99.1%

* Specificity data are not available in the Chinese study because the design of the studies focused on active TB disease, for which specificity is not a relevant metric. In China, the positive and negative predictive values for the diagnosis of active TB disease were 95.4% and 93.9%, respectively.

These data, which were generated in controlled studies under strict regulatory standards, demonstrate that our T-SPOT.*TB* test is able to detect TB infection with high accuracy. In addition, our T-SPOT.*TB* test has also been validated in approximately 400 peer-reviewed publications in scientific journals.

Guidelines for TB testing

We believe that clinical guidelines, which are recommendations issued by national medical societies or public health bodies, are a driving factor in a clinician's decision to use a specific diagnostic test. Our T-SPOT.*TB* test is included in clinical guidelines for TB screening in at least 17 countries, including the United States, several European countries, and Japan.

Guidelines typically refer to our T-SPOT.*TB* test generically as an IGRA. Guidelines generally incorporate one of four common approaches: (1) a two-step approach in which TST is administered and subsequently followed by an IGRA, either when the TST is negative (to increase sensitivity, mainly in immunocompromised individuals) or when the TST is positive (to increase specificity, mainly in BCG-vaccinated individuals); (2) either TST or IGRA, but not both; (3) IGRA and TST together (to increase sensitivity); and (4) IGRA only, replacing the TST.

In recent years, the use of IGRAs has been increasingly recommended. For example, key recommendations contained in the CDC's 2010 guidelines are as follows:

- An IGRA may be used in place of a TST in all situations in which the CDC recommends TST as an aid in diagnosing TB infection.
- An IGRA is preferred for testing persons from groups that historically have low rates of returning to have TSTs read.
- An IGRA is preferred for testing persons who have received BCG (as a vaccine or for cancer therapy).
- A TST is preferred for testing children under the age of five, though use of an IGRA in conjunction with a TST has been advocated by some experts to increase diagnostic sensitivity in this age group.

[Table Of Contents](#)

- An IGRA or a TST may be used without preference to test recent contacts of persons known or suspected to have active TB disease, with special considerations for follow-up testing. IGRAs offer the possibility of detecting *M. tuberculosis* infection with greater specificity than with a TST. Also, unlike TSTs, IGRAs do not boost subsequent test results and can be completed following a single patient visit.

We believe that these guidelines (and similar national guidelines outside the United States) allow us to access the vast majority of the current TST market and assert the superiority of an IGRA in significant segments of the market.

Market segments and revenue mix

We have a geographically diversified business. In 2014, 54% of our revenue was derived outside the United States and 46% inside the United States.

Our U.S. business derived 96%, 96% and 95% of revenue from our service offering (as opposed to kit sales) for the years ended December 31, 2014, 2013, and 2012, respectively. The growth in our service offering reflects our experience that U.S. customers prefer to send out for IGRA tests than run them in-house. We categorize the U.S. market into four main areas:

- *Hospital based-testing.* We estimate that there are 7.0 million tests performed in hospitals in the United States each year. This test volume is made up primarily of testing of hospital employees, although there is also some in-patient and out-patient testing of high-risk patient groups. Testing in this segment is primarily non-reimbursed, with the test costs borne by institutional budgets. Consequently, test pricing results from direct negotiation with each institution. Our current average selling price is approximately \$50 per test for this segment. We therefore believe that this segment has a total annual value of approximately \$350 million.
- *Public & student health.* We estimate that there are 1.5 million tests performed by public health and student health accounts across the United States each year. This test volume is made up of testing foreign born students attending U.S. schools and colleges, contacts of infectious TB patients, refugees and other immigrants and testing conducted in public health clinics, which covers testing for a wide variety of purposes. Testing in this segment is primarily non-reimbursed and thus subject to negotiated prices, although there are some testing populations in this segment that are covered by third-party payors. We currently collect approximately \$50 per test for this segment. We therefore believe that this segment has a total annual value of approximately \$75 million.
- *Physicians' offices and clinics.* We estimate that there are 7.3 million tests performed in physicians' offices and clinics across the United States each year. This test volume is made up of testing of various high-risk groups, including HIV patients, rheumatology patients and those undergoing immunosuppressive treatment regimens. Testing for these patients is typically reimbursed by Medicare, Medicaid and third-party commercial payors. Based on our experience to date with billing these payors, and our Medicare national limitation amount of approximately \$102 per test, we believe that we may be able to collect as much as \$75 to \$95 per test performed in this segment. Taking the mid-point of this estimate, this segment could have a potential annual value of approximately \$620 million.
- *Other.* We estimate that each year there are 6.0 million tests performed in various other settings, including military installations, correctional facilities and nursing homes. This test volume is made up of testing various groups, including military personnel, prisoners and prison workers, and residents and workers in long-term care homes. Reimbursement coverage and mechanisms vary based on the tested population. Because of our limited experience in this segment to date, we cannot currently estimate the potential annual value of this segment.

Currently, we derive the majority of our U.S. revenue from the hospital and the public and student health segments.

Our business outside the United States represents a total potential market of over 28 million tests annually. 91%, 90% and 83% of our revenue from outside the United States came from sales of kits and associated accessories, as opposed to service offering revenue, for the years ended December 31, 2014, 2013 and 2012, respectively. We, either directly or through our distributors, sell our testing kits primarily to hospital laboratories and commercial testing laboratories that perform the tests and provide test results to the ordering clinicians. Test prices are negotiated with each of our customers.

Funding and reimbursement

The funding and reimbursement structures for LTBI testing vary among countries, as discussed in more detail below.

United States

In the hospital, public health and student health segments, TB testing programs are funded primarily from institutional budgets. We receive payment from these institutions according to our pre-negotiated prices. For other segments of the U.S. market (notably, for example, the physicians' office segment) third-party reimbursement from governmental payors and/or private insurers is often available to cover the cost of our T-SPOT.TB test.

[Table Of Contents](#)

CPT codes are used by payors to identify services provided to patients and determine the appropriate level of reimbursement for such services. As such, obtaining a CPT code for a particular service facilitates payment to the provider. We applied for and were successful in obtaining a unique CPT code to cover our T-SPOT.TB test (code 86481), which became effective in January 2011. The reimbursement amount of this code was initially linked to CPT code 86480. We appealed this decision on the basis that our T-SPOT.TB test uses a different methodology and that this leads to differentiated clinical outcomes to the test covered under code 86480. Our appeal was successful and in January 2012 the reimbursement amount for code 86481 was increased by 22%. The current CMS national limitation amount for 86481 is approximately \$102. We have a national coverage determination for our CPT code 86481 from Medicare, which means we are able to obtain Medicare reimbursement nationally. Individual state agencies establish reimbursement levels for Medicaid. Our T-SPOT.TB test is currently reimbursed by Medicaid in 47 states and the District of Columbia, and our Oxford Diagnostic Laboratories®, or ODL®, facility is an enrolled provider with Medicaid in 42 states. Based on our experience to date, we believe the majority of insurers deem our test medically necessary and, therefore, cover our test.

There are a number of other segments of the U.S. TB screening market, such as correctional facilities, military personnel, university students and chronic care facility residents. We believe that funding varies within and among these segments, encompassing both funding from institutional budgets and from third-party payors.

Outside the United States

Although outside the United States we primarily negotiate pricing directly with our customers, our prices are influenced to some degree by the mechanism and level of funding our customers receive for testing for TB infection. The funding mechanisms for selected countries are explained below.

Japan. IGRAs are listed on the clinical lab fee schedule in Japan (code D015-25), which attracts a reimbursement level of ¥6,300 per test (or approximately \$53 per test based on a foreign currency exchange rate of \$0.00836/¥). We believe that this reimbursement code covers all patient testing done in hospitals and clinics. There also exists a mechanism to partially reimburse public health entities for IGRA testing from central government funds.

China. In China, test pricing is regulated by provincial and municipal government bodies. These bodies determine the price at which a test can be charged to the test recipient. To date, pricing approval has been granted for our T-SPOT.TB test in five provinces/municipalities. We believe that certain hospitals (e.g., military hospitals) fall outside of this formal pricing approval, in which case the test is funded from hospital budgets.

United Kingdom. No formal centralized reimbursement mechanism for diagnostic tests exists in the United Kingdom. Instead, the testing is funded from institutional budgets whether we sell kits or our service offering.

Germany. Outpatient testing is covered in Germany under the “EBM” reimbursement system. A code for IGRAs was established in January 2011 (Code 32670), which qualifies for reimbursement of €58 per test (or approximately \$70 per test based on a foreign currency exchange rate of \$1.21548/€). In addition, the cell-purification step inherent in our T-SPOT.TB test methodology can also attract an additional €10.40 per test (or approximately \$13 per test at the same exchange rate) in reimbursement. Testing that is not eligible for EBM reimbursement (e.g., inpatient testing and public health testing) is typically funded from institutional budgets.

Sales, marketing and distribution

We currently market our T-SPOT.TB test directly in the United States, Northern Europe and Japan. Outside of these territories, we have contracted with distributors who market and sell our test. In countries where we have a direct presence, we use a combination of sales managers, sales representatives, customer service staff and technical experts to interact with clinicians, nurses, administrative staff, laboratories and other groups who are involved in the implementation of TB screening programs. Our goal is to educate these groups about the medical, logistical and economic benefits of switching from the TST to our T-SPOT.TB test. Our customer service staff and technical experts are also involved in the practical training of customers to perform and order our T-SPOT.TB test as well as answering customer questions. These teams are supported by marketing activities, which include advertising, medical education, attendance at scientific meetings and other awareness-raising activities.

Our approximately 35,000 square foot U.S. ODL facility is located in Memphis, Tennessee, approximately ten miles from the FedEx global headquarters and sorting facility. We use FedEx as our courier for samples in the United States and have negotiated discounted shipment rates that our customers are able to take advantage of via our pre-paid specialized shipping containers. We believe that our location gives our laboratory the competitive advantage, being able to access almost all parts of the continental United States with a patient-to-lab time of typically less than 20 hours. In addition, we believe it gives us market access and convenience advantages because customers can use our service wherever there is a FedEx pick-up or drop-off location. Further, as we typically receive the majority of our packages from FedEx’s sort facility at 4 a.m., Memphis time, each morning we are able to achieve turnaround times that we believe are substantially quicker than other competing laboratories. Our U.S. ODL facility is College of American Pathologists accredited and has obtained the necessary Clinical Laboratory Improvement Amendments, or CLIA, registrations to accept samples from all 50 states.

Our U.K. ODL facility is located in an approximately 3,500 square foot laboratory facility in Abingdon, England. We use DX, which is the same courier used by U.K. National Health Service institutions, as our primary courier in the United Kingdom. Our U.K. lab is accredited to the ISO17025 quality standard. See “—Laboratory certification, accreditation and licensing” below.

Our technology platform

The immune system consists of three primary branches: innate immunity, humoral (or B cell based) immunity and cellular (or T cell based) immunity. Our proprietary T-SPOT technology platform allows us to efficiently measure marker-specific T cell and innate immune responses at a single cell level and thereby inform the diagnosis, prognosis and monitoring of patients with immune-regulated conditions.

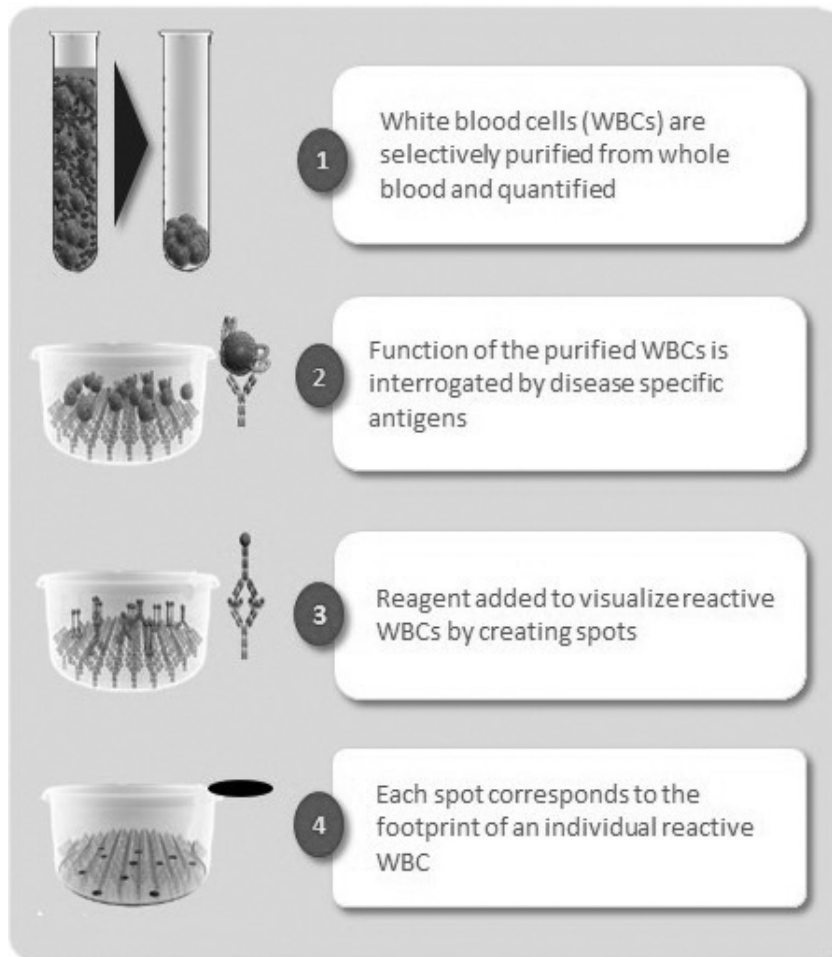
[Table Of Contents](#)

We employ a proprietary quantitative method to detect antigen-specific cells releasing immune messenger molecules, called cytokines, released by effector T cells or innate immune cells. In relation to effector T cells, our technology is designed to selectively measure responses from this subtype of T cells because they are primarily present when active, replicating pathogens are inside the body, as opposed to other T cell subtypes that may be present long after an infection has been cleared from the body. For diagnosis and monitoring applications, it is more relevant to be able to measure the immune response associated with the current infection rather than the immune response associated only with past, cleared exposure.

The principles of our T-SPOT assay system are shown in Figure 1.1 below, using blood as the body fluid in the example.

Simplistically, the technology starts with a blood sample obtained through a standard blood collection tube from which white blood cells, or WBCs, are separated. The cells are quantified and placed into specially designed plates where they are challenged with antigens specific to the disease under study. We then use chemistry to allow us to visualize those WBCs which react to the antigen, resulting in a spot on the bottom of the plate, corresponding to the footprint of an individual reacting WBC. Finally, we use an automated image analysis system to identify and count each of these spots, to give a quantitative readout.

Figure 1.1 T-SPOT technology



[Table Of Contents](#)

Key features of this assay method that give it technical advantages over other platforms include:

- *High analytical sensitivity.* Our analytical method measures responses of T cells and innate immune cells at a single-cell level, which allows high analytical sensitivity. We are able to reliably detect specific cell responses at frequencies of 1 per 50,000 WBCs or less.
- *Application to other diseases and conditions.* By altering the target-specific antigen used in our T-SPOT assay, we can direct our technology platform to detection of different diseases or conditions where T cell or innate immune function is involved. Our proprietary methods can be used to visualize cytokines other than IFN- γ and our methodology can be and has been successfully applied to other body fluids. This provides us the ability to detect cell responses not just in the bloodstream, but also from T cells and innate immune cells that have migrated to sites of disease.
- *Low background noise.* Our cell separation procedures ensure that subsequent steps of the process start with a purified and clean sample. Our assay system therefore has a low background noise that is essential for the detection of weaker responses, which is critical in many applications, including screening for TB infection.
- *Standardization.* We standardize the number of WBCs added to each well, which ensures that variations in WBC numbers, such as those caused by disease or immunosuppression, are eliminated prior to starting the assay. This is particularly relevant in populations with lower numbers of WBCs, such as HIV patients and other immunocompromised groups, including transplant patients. In addition, standardization of the number of WBCs is important to establish a stable baseline against which to validly compare longitudinal measurements within an individual. This standardization is thus important for disease monitoring indications.
- *Ability to ship blood samples overnight.* We believe our intellectual property position that covers both positive and negative selection to stabilize a fresh blood sample gives us an advantage in that we can ship blood overnight and automate the cell separation step of the assay. We believe this allows for much easier adoption of our technology, as customers do not need to go through labor-intensive freezing protocols prior to shipping samples and widespread access to the test can be accomplished without the need for a suitable local lab to run the test. In addition, overnight shipment allows the centralization of samples in a single testing facility, such as our ODL facilities, which can yield cost savings through economies of scale and gives us the advantage of building direct relationships with the individuals and organizations who order the tests. Finally, automation reduces overall costs in running the tests for both us and our customers.
- *Designed to be incorporated in standard clinical practice.* The sample collection process is designed to be easy to perform in a wide variety of clinical settings using a standard blood draw. By using industry-standard sample collection procedures, we believe our T-SPOT.TB test and subsequent assays we develop using our T-SPOT platform will be accessible to a wide variety of customers.

Our platform relies in part on our patented method for stabilizing blood samples to allow them to be processed after they have been shipped overnight. This method involves the removal of contaminating granulocytes from the shipped sample to rejuvenate it prior to processing. Granulocytes are a normal component of whole blood. However, once blood is removed from the body, granulocytes start to progressively decay, which can cause contamination of the WBC components of interest. In addition, decaying granulocytes release chemicals that can suppress cytokine secretion, further reducing test sensitivity. By removing granulocytes prior to starting an assay, we restore the sample to the same composition and function as a fresh sample.

Historically, we have commercialized our blood stability technology through the use of our T-Cell *Xtend* reagent in conjunction with our assay methodology. The T-Cell *Xtend* reagent is an antibody complex that binds granulocyte cells to red blood cells, thereby ensuring that they do not contaminate the WBC components used in our assay. By using the T-Cell *Xtend* reagent, we can test blood samples that have been shipped and/or stored for up to 32 hours before processing commences. We have also recently validated an alternate blood stability process that leverages our patented method while allowing for automation of initial cell separation. Specifically, we have developed a process using magnetic bead technology to positively select the blood cells needed for our test. Magnetic bead technology will be used in our next generation T-SPOT.TB test.

The blood stability processes covered by our patent address the significant process limitation inherent in some laboratory tests that require a fresh blood sample for the assay. When this requirement exists, the diagnostic test may not be accessible for many subjects unless a local laboratory is available and able to quickly process the sample. An alternative approach is sometimes employed in which blood samples are carefully frozen before shipment to a laboratory. We believe this approach is impractical in regular clinical use, particularly when a large volume of samples is involved, and reduces sample quality. Our patented processes address this problem without the need for freezing the blood. Specifically, our solutions do not require the customer to do anything to process blood samples prior to shipment, making them practical for routine clinical use and significantly broadening the potential market for certain diagnostic tests.

We also employ proprietary manufacturing processes and protocols designed to cost-effectively and reliably produce key elements of our T-SPOT technology, including the process for coating microtiter plates with cytokine antibodies, such as IFN- γ antibodies, and our quality control testing procedures. Further, we have developed proprietary methods designed to achieve rapid throughput in assay performance. These methods involve specific protocols throughout the assay process.

[Table Of Contents](#)

As scientific knowledge increases regarding the potential utility of measuring T cell and innate immune cell function to inform disease diagnosis and outcomes, we expect to have further opportunities to develop tests for various immune-regulated conditions, including those presently in our development pipeline. We believe our technology platform will provide us with significant competitive advantages in this effort and enable us to become a leader in the field of immunology diagnostics.

Research and development

Our research and development efforts are focused on developing new diagnostic tests that use our quantitative T cell measurement technology, in addition to building on the innate immune system technologies acquired from Boulder Diagnostics, Inc., or Boulder.

Our focus

Our research and development activities focus on developing and commercializing proprietary tests for the management of immune-regulated conditions. Large populations of patients have immune-regulated conditions that are often chronic conditions requiring active management through monitoring. These conditions also tend to be characterized by a wide variation in presentation and disease progression and expensive therapies. Testing that allows better categorization of patients and yields insights into the most likely successful treatment path facilitates more personalized medicine, directing therapies to patients in whom they are more likely to work and saving healthcare dollars.

Understanding immune-regulated conditions requires interrogation of the immune system. The human immune system is composed of three principal branches: innate immunity, cellular (T cell) immunity and humoral (B cell) immunity. Cellular and humoral immunity comprise the adaptive immune system. The majority of diagnostic tests available today focus only on antibody testing, which is one component of only the humoral immune system. Development of tests targeting T cells and the innate immunity system offers opportunities to aid the diagnosis, prognosis and monitoring of immune-regulated conditions. Our research and development efforts will continue to focus on utilizing our proprietary T cell and innate immunity technologies to bring new diagnostic tools to market to aid clinicians in diagnosing and managing immune-regulated conditions.

Immune-regulated conditions encompass a broad spectrum. We are focused on four principal areas: chronic infections, transplantation, autoimmune and inflammatory disease and immune-oncology.

- Chronic infections where progression is dictated by the strength of the patient's immune system are often called latent or opportunistic infections. Examples are infections such as TB and CMV, which are carried for long periods of time but may reactivate into disease at any point when the immune system is no longer keeping the infection under control. Persons with weakened immunity – including HIV patients, transplant recipients, and users of biologic therapies – are at particular risk.
- In transplantation, the success of the transplant depends on the accommodation of the donor organ by the host immune system. Extensive immune suppression accomplishes this goal but requires careful modulation to balance the considerable side-effects of immune suppression with rejection risk. Given the high demand for donor organs, strategies to maximize graft survival and to predict rejection events are necessary to improve patient care.
- Autoimmune and inflammatory diseases affect approximately 10% of Americans and include rheumatoid arthritis, systemic lupus erythematosus and Crohn's disease. These conditions present in wide variation and take multiple progression pathways. Tools that can better categorize patients and allow practitioners to tailor therapies to meet the individual needs of patients may improve the quality of care while simultaneously reducing healthcare costs.
- Cancer is at a simplistic level an immunological disease. The patient's T cells either do not recognize the tumor as foreign or the tumor successfully down-regulates the T cells. New immune-oncology cancer therapies focus on increasing the efficacy of the body's own immune system to fight the tumor. We believe that diagnostic tools that measure the status of the anti-tumor immune response have the potential to guide therapeutic drug development as well as inform treatment decisions.

Our pipeline

We have seven programs in active development, each directed to one of our four areas of focus. Our most advanced program is the T-SPOT.*CMV* assay, a test to measure the immune response to CMV infection. Our next program is the T-SPOT.*PRT* assay, which helps to inform organ rejection. The T-SPOT.*ICA* assay is an immune-competence assay that like our T-SPOT.*CMV* and T-SPOT.*PRT* assays is directed to the transplant space. We have three products targeting the autoimmune and inflammatory disease area: our SpiroFind assay, targeting Lyme disease; GoutiFind, targeting gout; and Stratokine, targeting efficacy of biologic therapies. Finally we have an early stage immune-oncology program through which we are investigating the use of T-SPOT technology platform in cancer immunotherapy. We discuss each development program in brief below.

Transplant Products

Over 150,000 transplants were conducted in 2011, distributed roughly equally throughout the world with 29% in the United States, 34% in Europe and 37% in the rest of the world. Kidney and human stem cell transplants form the majority of the market. The majority of transplants are performed in hospitals or clinics specializing in organ or stem cell transplant, presenting a fairly concentrated sales call point. Our three products currently in development targeting the transplant market are T-SPOT.*CMV*, T-SPOT.*PRT* and T-SPOT.*ICA*.

[Table Of Contents](#)

Our T-SPOT.*CMV* assay assesses the strength of a patient's cellular immune response to CMV, giving an indication of likely susceptibility to CMV infection. CMV is a chronic persistent infection and an opportunistic pathogen. It is present in up to 90% of the human adult population, most of whom successfully control its progression through their T cell response. For those with weakened immune systems such as transplant recipients, however, CMV presents a significant source of morbidity. Our T-SPOT.*CMV* test is directed to measurement of the strength of the T cell response to CMV and, therefore, may be a useful aid in evaluating a patient's risk from CMV disease.

Our T-SPOT.*PRT* assay measures the functional response of an organ recipient's T cells to a panel of antigens representing foreign tissue types. Present test methods directed to assessing the likelihood of graft rejection focus only on antibody mediated rejection. Graft rejection often involves the activation of T cells. Our test is directed to inform the risk a T cell mediated rejection both pre- and post-transplant, potentially allowing clinicians to reduce rejection events and adjust immunosuppression consistent with the patient's T cell response to the graft.

Finally our T-SPOT.*ICA* assay measures the competence of T cells, with the goal of providing a score that is tracked over time to evaluate the functional strength of the T cell immune system. This test quantitatively assesses the degree of T cell suppression as a result of immunosuppressive therapies or other immunodeficiency. In the context of transplantation, while immunosuppression is necessary to reduce the risk of graft rejection, too much immunosuppression risks significant long and short term side effects, including nephrotoxicity, life-threatening infections (like CMV, Epstein-Barr virus and BK Virus) and cancer. By measuring overall competence of T cells, this test may provide clinicians with additional tools to manage immunosuppression while also providing greater insight into effective therapies, resulting in better outcomes and cost savings. The T-SPOT.*ICA* assay may also have utility in the field of immune-oncology.

We estimate the current market for our T-SPOT.*CMV*, T-SPOT.*PRT* and T-SPOT.*ICA* tests to be in the range of \$500 million to \$900 million.

Autoimmune and Inflammatory Disease

We have three assays in development in the area of autoimmune and inflammatory disease, each of which we acquired from Boulder in 2014. These assays interrogate the innate immune system.

The first assay, presently referred to as SpiroFind, targets Lyme disease, a disease that affects approximately 300,000 Americans annually and has been reported in 80 countries. Lyme disease is caused by exposure to *Borrelia burgdorferi* commonly in the form of an insect bite, most commonly a tick bite. Lyme disease presents with a host of symptoms mimicking other diseases and, therefore, constitutes a unique challenge for clinicians. Current Lyme disease tests take weeks to demonstrate positivity, lack sensitivity and cannot distinguish between new infection and prior infection. Our assay in development may provide both an earlier diagnosis and the ability to differentiate re-infections from prior exposure.

The second assay targets gout, an inflammatory disorder that usually presents with an acutely swollen painful joint, typically the big toe. While fine needle aspiration of the joint and identification of typical monosodium urate crystals under polarizing microscopy confirm the diagnosis, the procedure is painful and not well suited for many primary care physician offices. Our test is a simple blood test, presently named GoutiFind, that may allow early diagnosis and better inform therapies by measuring the strength of the underlying uric acid induced inflammation.

Our final assay in this area targets the selection of the most appropriate immune-modulating biologic therapies for patients. Biologic therapies are increasingly prescribed for various autoimmune and inflammatory diseases such as rheumatoid arthritis, psoriasis, ulcerative colitis and Crohn's disease, often with no means of knowing if the chosen therapy will be effective. Our Stratokine test is an immune profiling assay that interrogates cytokine pathways to identify most and least active response pathways allowing better selection of the biologic therapy.

[Table Of Contents](#)

Immune-oncology

Our work in the area of immune-oncology remains in the early stages as we explore the areas of utility of our T-SPOT platform in the context of cancer immunotherapy. In addition to evaluating use of our platform in connection with the development of vaccines or therapies targeting specific cancer cell surface antigens, we are also investigating use of our technology in connection with adoptive T cell therapy and checkpoint inhibitors. As our research in this area progresses, we will be refining our focus with the goal of optimizing the commercialization of our T-SPOT platform in the immune-oncology space.

Our research and development expenses were \$7.0 million, \$2.1 million, and \$1.9 million for the years ended December 31, 2014, 2013, and 2012, respectively.

Intellectual property

We seek to secure and maintain protection of the proprietary aspects of our technology platform and of our existing and planned products. We rely on a combination of patents, trademarks, trade secret and other intellectual property laws, and confidentiality, license and invention assignment agreements and other contracts to protect our intellectual property rights. In addition, we have developed substantial knowledge in the field of immunology diagnostics including proprietary methods that we believe provides us with a significant advantage relative to potential competitors.

The intellectual property relating to our T-SPOT.*TB* test that we own or license includes 12 issued U.S. patents, more than 20 issued patents in other jurisdictions, four pending U.S. patent applications and five pending patent applications in other jurisdictions, as well as registered trademarks, proprietary manufacturing processes and protocols, and proprietary methods directed towards achieving rapid throughput in assay performance.

Our owned and licensed patents

The table below identifies the patents and pending patent applications we own or to which we have license rights that relate to our T-SPOT.TB test.

Patent and patent application numbers(1)	Form of rights(2)	Expected expiration date	General description of subject matter
US 7,575,870, US 8,617,821, US 14/090,221*, EP 941478, JP 4094674, AU 728357, CA 2,272,881	Owned(3)	November 2017	Methods, including use of ELISPOT technique, to detect and quantify <i>in vitro</i> effector T cells that respond to pathogen specific antigen stimulation with the release of interferon-gamma
EP 2084508, CN 101529221, US 13/253,598*, JP 2009-530943*, JP 2013-257625*, AU 2007303994, CA 2,665,205*, IN 2165/DELNP/2009*	Owned	October 2027	Methods of improving stored blood sample stability by removing granulocytes
US 7,115,361	Owned(3)	December 2019	Method and kit for detecting TB specific T cells following stimulation with antigen peptides
US 7,632,646, US 7,901,898, US 8,216,795, US 8,507,211 US 13/940,758*, EP 1144447, JP 4633931, ZA 2001-3356	Owned(3)	November 2019	Composition, method and kit for diagnosis of TB using peptides from ESAT-6
US 6,290,969, US 8,084,042, EP 1203817, JP 4324597, CN 1117149, AU 727602, CA 2,653,566, ZA 9607394, and a number of other countries	In-licensed from Statens Serum Institut	September 2015 (US) August 2016 (other jurisdictions)	Composition and method of making an isolated polypeptide of TB specific protein CFP10
US 5,955,077	In-licensed from Statens Serum Institut	September 2016	Composition and sequences of TB polypeptide antigen ESAT-6 and uses in diagnosis of TB
US 7,579,141, US 8,021,832, US 14/201,308*, EP 1214088, EP 2087906*, JP 4820489, AU 773268, CA 2,372,583	In-licensed from Rutgers, The State University of New Jersey	May 2020	Methods of <i>in vitro</i> diagnosis utilizing the T cell response to CFP10 to distinguish between exposure to TB and BCG vaccination

* Reflects pending patent applications

(1) Where we have rights to patents granted by the European Patent Office, or the EPO, the patents have been validated in numerous countries in Europe, which vary by specific patent but typically include at least the United Kingdom, Germany and France.

[Table Of Contents](#)

- (2) For a discussion of the terms of the licenses referenced in this table, please see “—Our license and assignment agreements” below.
- (3) These patents were assigned to us by Isis Innovation Limited in November 2013. For a discussion of our ongoing payment obligations to Isis Innovation Limited and other rights related to these patents, please see “—Our license and assignment agreements” below.

Many of the patent rights we own or in-license have claims directed to the use of ESAT-6 and/or CFP10 to detect *Mycobacterium tuberculosis*. We believe that these are the most important TB-specific antigens and we include peptides from both of these in our T-SPOT.TB test. We also believe that using an ELISPOT technique for an IGRA enhances its accuracy and suitability for use in testing individuals with compromised immune systems. Our T-SPOT.TB test employs this technique.

The first two patent groups listed in the table above also have potential applications beyond the TB field. The core technology patents, which we own, contain claims to methods of measuring marker-specific effector T cell responses at a single-cell level. These methods cover the measurement of intracellular pathogens by detecting, through a quantitative method using an ELISPOT technique, the *in vitro* release of cytokines by antigen-specific effector T cells. These measurements can inform the diagnosis, prognosis and monitoring of patients with immunologically controlled diseases or conditions, such as infectious diseases, cancers and autoimmune diseases.

The inventions claimed in our patents and patent applications relating to removal of granulocytes from stored blood samples may also have applications in relation to other diseases, conditions or situations where blood samples cannot be tested soon after the blood draw. This proprietary method to improve the stability of stored blood enables our service offering as it allows for overnight shipment of blood samples. Our next generation T-SPOT.TB test leverages this patent.

We have also licensed certain patent rights that we believe may assist us to develop future diagnostic tests, particularly in the transplant and autoimmune fields. The expected expiration dates of these patents range from March 2018 for three issued U.S. patents to which we have non-exclusive rights to May 2027 for pending patent applications to which we have exclusive rights for *in vitro* diagnostics measuring immune status in humans related to organ transplantation, graft versus host disease and autoimmune disease. We also have licensed certain patents related to the technology acquired from Boulder that may provide coverage for future diagnostic tests beyond 2030. We can give no assurance that any of our current or future research and development programs will result in the development and validation of any diagnostic test.

Our license and assignment agreements

We currently rely upon two license agreements, referenced in the table above, to obtain rights under certain patents that we believe may be necessary to make, use and sell our T-SPOT.TB test. We may in the future rely, at least in part, upon licensing agreements with third parties to obtain patent rights and transfers of technology, information and know-how to enable us to take advantage of research work already completed, including potentially the identification of antigens useful for measuring disease conditions. We believe such licensing arrangements have enabled us, and may in the future enable us, to reduce the amount of time we need to develop and validate new diagnostic tests.

We have royalty obligations under each of our license agreements and also have payment obligations, measured in part based on our sales levels, under the terms of the assignment agreement by which we acquired rights to certain of the patents we currently own. For ease of presentation in this Annual Report, we include all payments measured by sales levels as royalty obligations. Our royalty obligations are calculated on our net sales, the definition of which varies by agreement and typically results in a lower effective royalty rate on our service revenue than on sales of our kits. Currently, our aggregate royalty burden under all license and assignment agreements, as a percentage of gross product and service revenue, is in the low double digits. Under one of our license agreements, we are responsible for paying, or contributing to, patent prosecution and maintenance costs. Both of the license agreements related to our T-SPOT.TB test and our assignment agreement impose diligence obligations on us. These obligations include certain requirements relating to the pursuit of clinical development and commercialization of licensed products in various markets worldwide. We believe we are in compliance with such obligations.

Isis Innovation Limited (Isis)

In connection with our initial public offering, we entered into an assignment agreement with Isis, pursuant to which various patents we previously licensed from Isis were assigned to us. We have ongoing obligations under the assignment agreement to make payments to Isis until the patents expire and to continue to extend license rights to the University of Oxford, its employees, students, agents and appointees to use the technology for academic and research purposes. Our rights under the patents assigned to us by Isis are subject to various grants of license rights, including (i) a license back to Isis to maintain a pre-existing license for research use only, (ii) a pre-existing grant to a third party of non-exclusive rights under the patents covering a field of two infectious diseases, (iii) a pre-existing grant to a third party of non-exclusive rights under the patents limited to the licensee’s internal use to monitor vaccine response, and (iv) a pre-existing grant to a third party of non-exclusive rights under some of the patents with the right to sublicense, limited to use with ESAT-6 and CFP10 antigens, and excluding use of the ELISPOT technique for diagnosis and monitoring of TB infection, disease or therapy. We do not believe this third party has granted any sublicense rights as of December 31, 2014.

[Table Of Contents](#)

The amount we pay to Isis for our royalty obligation is equal to a royalty rate in the low single digits and we expect this rate to be reduced for certain of our sales after the expiration of certain specified patents, which we believe will be in late 2017. Our aggregate royalty obligation payments to Isis through December 31, 2014 have been \$1.3 million. Our royalty obligations to Isis will cease when there are no valid patent claims still in force.

Statens Serum Institut (SSI)

We entered into our current license agreement with SSI in 2009, replacing an original license agreement from 2003. The current license agreement has been amended by one supplement entered into in 2010.

Pursuant to the agreement, SSI granted us an exclusive, worldwide, royalty-bearing license with the right to sublicense, to certain patents to use certain antigens in a diagnostic kit for *in vitro* diagnosis of TB in humans using an ELISPOT-based detection of interferon-gamma producing T cells using any fluid sample other than whole blood in the diagnostic assay. We have not granted any sublicenses under this license.

Previously, we made a number of milestone payments due under the license to SSI, although no future milestone payments are required. We pay royalties in the Euro currency at a rate between 10-20% of net sales, as defined in the agreement, subject to minimum annual royalty payments, which vary by territory. Through 2019, we may be required to make minimum royalty payments for three territories in aggregate amounts of \$3.7 million, \$4.4 million, and \$3.0 million. The license agreement provides that royalty obligations continue after the expiration date of licensed patents for a period of four years at a single digit royalty rate. Our aggregate payments to SSI through December 31, 2014 for milestones and royalties, including minimum royalties, have been \$10.7 million.

Our license agreement expires, unless earlier terminated, five years after the expiration of the last to expire of individual licensed patents listed as part of the agreement at the effective date in 2003. SSI may terminate the agreement if we, or any future sublicensees, challenge the licensed patents or other SSI intellectual property covered by the agreement. The agreement provides that either party may terminate for material uncured breach by the other party or for certain bankruptcy or insolvency events involving the other party. SSI may also terminate the exclusivity of the license and cease licensing improvements to us if we engage in certain activities related to the development or commercialization of a diagnostic test for latent tuberculosis that does not incorporate any of the licensed diagnostic antigens and which competes with research into, development of or commercialization of the intellectual property rights licensed to us.

Rutgers, The State University of New Jersey (Rutgers)

We entered into our license agreement with Rutgers in 2006 and it has been amended four times, in 2009, 2011, 2012 and 2013. Pursuant to the agreement, Rutgers granted us an exclusive license to certain patents to manufacture and commercialize kits for *in vitro* diagnostic assays relating to TB other than in the ELISA format. Our license is royalty-bearing, worldwide, with the right to sublicense. We have not granted any sublicenses under this license. Rutgers has reserved the right to grant one additional license to this technology, limited to an ELISA format. To date, we do not believe Rutgers has entered into any such license.

We must make semi-annual royalty payments to Rutgers. Although the agreement contains minimum royalty obligations, the amount of royalties due based on our actual sales has exceeded the minimum for a number of years and we expect our obligations will continue to exceed the minimum for the duration of our royalty obligations. We pay a royalty rate in the low single digits. Our aggregate payments to Rutgers through December 31, 2014 for signing fees, annual fees, milestones and royalties, including minimum royalties, have been \$2.6 million. Our royalty rate may be reduced, depending on the outcome of an European Patent Office, or EPO, opposition appeal and could also be reduced if Rutgers grants another license to the technology covering an ELISA format. See “Risk factors—Risks related to our intellectual property.” Our royalty obligations to Rutgers will cease when there are no valid patent claims still in force covering licensed products or assays. Previously, we made a number of other payments to Rutgers for license issue fees, annual license fees and milestone payments. No such future payments are required under the license.

Rights under the agreement expire on the last to expire of the licensed patents or the abandonment of all patent applications related to the licensed patent rights. We may terminate the license by advance written notice. Either party may terminate the license for material uncured breach by the other party. Rutgers may terminate the license if a court or administrative body finds it liable or culpable due to our performance, or the performance of any future sublicensee, unless we agree to indemnify it from damages resulting from the decision. Our license rights terminate automatically if any bankruptcy, insolvency or similar proceedings are instituted by or against us (subject to reinstatement if the matter is removed within a specified time frame).

Trademarks and other protection

The trademarks we employ in our TB screening business include T-SPOT, T-Cell *Xtend*, Oxford Diagnostic Laboratories, ODL, the Oxford Immunotec logo and our laboratory logo. We have obtained registrations in the United States for T-SPOT, T-Cell *Xtend*, Oxford Diagnostic Laboratories and the Oxford Immunotec logo. We have also obtained or are seeking registrations for certain of these trademarks in other jurisdictions, including the United Kingdom, the European Community, Japan and China. We have also secured numerous domain name registrations.

[Table Of Contents](#)

We have a policy of requiring all our employees to sign agreements that obligate them to maintain in confidence all confidential information they receive during the course of their employment, except in certain circumstances. Substantially all of our employees are also bound by invention assignment obligations, which provide that rights to all inventions and other types of intellectual property, whether or not patentable, conceived by them during the course of employment are assigned to us. We seek to enter into similar confidentiality and invention assignment agreements with our consultants.

Our proprietary processes

There are several areas in which we have developed proprietary approaches to manufacturing that we believe provide a competitive advantage not only with respect to our T-SPOT.*TB* test, but also for future tests we may develop on our T-SPOT technology platform. It is essential to the performance of ELISPOT tests used to detect the release of interferon-gamma from stimulated T cells that the microtiter plates used in the test be smoothly coated with the proper amount of interferon-gamma antibodies. For volume manufacturing, these coated plates must also meet stringent shelf life requirements. Our plate-coating process meets these criteria and cost-effectively provides reliable results. We have also developed a proprietary approach to conducting conformance testing and validation as part of our quality control processes. We believe this approach results in significant cost savings for us without sacrificing our compliance with either good manufacturing practices or our own high standards.

As part of our T-SPOT.*TB* test, we use a proprietary formulation of peptides which we believe is important to the accuracy of our test. Further, we have devoted substantial time and resources to the development of processes and techniques that have resulted in cost reductions in our test manufacture and in assay performance in our service laboratories. In our ODL facilities, we have streamlined the workflow process in our laboratories to allow for rapid throughput, which reduces labor costs and reduces the time we take to provide test results to our customers. In addition, we have developed and validated automated solutions for the assay process, including proprietary protocols for maximizing efficiencies garnered from the automation equipment. These methods are useful in our T-SPOT.*TB* test, and will be applicable to future tests we may develop using our T-SPOT platform. We believe the manufacturing process and assay performance efficiencies we have developed and employ could not easily or quickly be developed by others.

Manufacturing and laboratory facilities

Our T-SPOT.*TB* test is generally manufactured by us from materials we obtain from a limited number of suppliers. We manufacture our product at our U.K. corporate headquarters in Abingdon, England, where we currently lease approximately 6,937 square feet of laboratory space, including the space dedicated to product manufacturing. Our manufacturing facility is certified to ISO 13485 and ISO 90001. The lease on this facility expires in 2019 and our current rent for the manufacturing facility is \$328,000 annually, which is subject to change.

We operate two diagnostic testing laboratories, one in the United States and one in the United Kingdom, where we process samples sent to us by our customers who choose the service format of our T-SPOT.*TB* test offering. Our U.S. laboratory facility is located in Memphis, TN, where we currently lease approximately 35,000 square feet of space. The lease on this facility expires in 2021. Our current rent under this lease is \$146,000 annually and is subject to annual increases. Our U.K. laboratory is located in Abingdon, United Kingdom, where we currently lease approximately 3,500 square feet of space. The lease on this facility expires in 2019 and our current rent for the laboratory space is \$88,000 annually.

Key supplier relationships

Mabtech AB. We entered into a purchase agreement with Mabtech AB, or Mabtech, in 2010, which was amended in 2013. Pursuant to this agreement, Mabtech supplies the antibodies used to coat the membrane plates and for the detection procedure in our T-SPOT.*TB* test. We provide rolling forecasts of our anticipated purchases and portions of those forecasts become binding orders. We receive pricing discounts based on the volume of our purchases. We have agreed to purchase these antibodies exclusively from Mabtech, although our exclusivity obligations may cease in the event Mabtech raises prices by more than a certain percentage over a defined period of time and declines to match a competitive third-party quotation for the antibodies.

The purchase agreement expires, unless earlier terminated, on December 31, 2018. Either party may terminate by providing written notice to the other in the event of a material uncured breach by the other party, a liquidation, insolvency, or bankruptcy proceeding involving the other party or cessation in trading by the other party.

We also entered into a manufacturing agreement with Mabtech in 2003, which was amended in 2010 and again in 2011. Pursuant to the manufacturing agreement, Mabtech supplies us with antibody-coated membrane plates, using plates we purchase from another supplier and provide to Mabtech. These antibody-coated membrane plates are a component of our T-SPOT.*TB* test. We provide rolling forecasts of our anticipated purchases and portions of those forecasts become binding orders. We receive pricing discounts based on the volume of our purchases.

The manufacturing agreement expires, unless earlier terminated, on December 31, 2016. Either party may terminate by providing written notice to the other in the event of a material uncured breach by the other party, a liquidation, insolvency or bankruptcy proceeding involving the other party or cessation in trading by the other party.

[Table Of Contents](#)

EMD Millipore Corporation. We entered into a supply agreement with EMD Millipore Corporation, or Millipore, in 2009, which was amended in 2013 and 2014. Pursuant to this agreement, Millipore supplies us with the membrane plates used in our T-SPOT.*TB* test. We provide rolling forecasts of our anticipated purchases and portions of those forecasts become binding orders. We receive pricing discounts based on the size of our orders. The agreement expires, unless earlier terminated, on December 31, 2018. Each party has the right to terminate in the event of a material uncured default by the other party.

MicroCoat Biotechnologie GmbH. Pursuant to our 2010 supply agreement with MicroCoat Biotechnologie GmbH, or MicroCoat, MicroCoat performs antibody coating on membrane plates using plates and antibodies we supply. Under the supply agreement, we provide rolling forecasts of our anticipated purchases and portions of those forecasts become binding orders. We receive pricing discounts based on the size of our orders. These antibody-coated plates are a component of our T-SPOT.*TB* test.

The agreement expires, unless earlier terminated, on December 31, 2015, subject to automatic renewals for additional one-year periods in the absence of specified notice by either party. Each party has the right to terminate in the event of a material uncured breach by the other party, or in the event of a bankruptcy or insolvency proceeding involving the other party.

StemCell Technologies, Inc. We entered into a supply agreement with StemCell Technologies, Inc., or StemCell, in 2008, which was amended in 2011. Pursuant to this agreement, StemCell supplies us with a product that can be used in performing an assay with our T-SPOT.*TB* test.

We have the exclusive right to market this product for use in association with ELISPOT tests to detect and/or quantify T-cells for use in the *in vitro* diagnosis, prognosis and/or clinical monitoring of infectious diseases (including tuberculosis) and non-infectious diseases and medical conditions, except our rights in China and India are non-exclusive. StemCell retains the right to sell this product for use in other applications and in our non-exclusive territories. We are obligated to use commercially reasonable efforts to promote sales of the product for the applications to which we have exclusive rights.

We paid a signing fee in the amount of \$0.1 million and milestone payments in the aggregate amount of \$0.2 million. We are not obligated to make additional milestone payments. We are obligated to pay an annual exclusivity fee during the term of the agreement, creditable against certain future purchases. The aggregate amount of exclusivity fees due under the agreement is, absent early termination, \$1.8 million. Our product purchases exceeded the amount of the exclusivity fee in 2014, and we expect we will continue to exceed this minimum in 2015. We receive pricing discounts based on our quarterly orders. We have also agreed to make StemCell our supplier of choice for certain types of products, subject to performance obligations of StemCell, and we are generally obligated to acquire all of our requirements for such products from StemCell.

The agreement expires, unless earlier terminated, on January 30, 2018, but will continue indefinitely thereafter in the absence of specified notice by either party. Each party may terminate for material uncured breach, the insolvency or bankruptcy of the other party or the cessation of trading by or dissolution of the other party. If we terminate the agreement for other reasons prior to January 30, 2018, we may be obligated to pay a termination fee of up to \$0.5 million to the extent that we have not previously made other payments for the signing fee, milestone payments and actual product purchases in excess of this amount. Based on our payments to date, we do not expect to incur any termination fee if we terminate the agreement.

Life Technologies Corporation. We entered into a supply and reseller agreement with Life Technologies Corporation, or Life Tech, in 2013, amended in 2014, pursuant to which we purchase and resell a product that can be used in performing an assay with our T-SPOT.*TB* test. We have minimum annual purchase obligations under this agreement, as well as obligations to purchase certain amounts based on our forecasts. The agreement expires, unless earlier terminated, on January 1, 2017. Either party may terminate for a material uncured breach, the insolvency or bankruptcy of the other party, if one of our twelve-month forecasts does not reflect any anticipated purchases of product or if we purchase no product during a consecutive twelve-month period.

Key customer relationships

Shanghai Fosun Long March Medical Science Co. Ltd. We have a distribution agreement with Shanghai Fosun Long March Medical Science Co. Ltd., or Fosun, pursuant to which Fosun distributes our products in China. Under the distribution agreement, Fosun serves as our exclusive distributor in a territory consisting of the People's Republic of China, including Macau Special Administrative Regions, and also serves as our non-exclusive distributor in Hong Kong. Fosun commits to using its best efforts to promote, sell and distribute our products in the territory in compliance with our policies and procedures and applicable law. The agreement imposes certain annual minimum purchase obligations at agreed upon pricing and covers our products, as well as other accessories which may be used in conjunction with our products. Fosun is obligated to refrain from dealing in any products in the territory which would be competitive with ours through a period extending 12 months after the termination of the agreement. Fosun is a related party. See Note 12 "Related party transactions" for additional information pertaining to Fosun.

The agreement expires on January 1, 2021. Either party may terminate the agreement for a material uncured breach or in the event of bankruptcy or an equivalent winding up of the other party's business. We may terminate the agreement if Fosun does not meet the minimum purchase requirements, for late payment or if Fosun undergoes a change in control.

[Table Of Contents](#)

Riken Genesis Co., Ltd. We sell our T-SPOT.*TB* test to a Japanese importer, Riken Genesis Co., Ltd., or Riken, which also serves as our marketing authorization holder in Japan, a position required by Japanese regulatory authorities. We entered into a marketing authorization holder agreement with Riken in 2011 and it was amended in 2013. Pursuant to this agreement, Riken provides services for importation into Japan. We paid an initiation fee to Riken in the amount of ¥200,000, or approximately \$2,000. We pay Riken a flat monthly fee in the amount of ¥150,000, or approximately \$1,500, and also pay a single-digit percentage commission based on the prices at which end users purchase our products. The initial agreement with Riken had a one-year term and automatically renews for additional one-year periods in the absence of specified notice by either party. Either party may terminate for a material uncured breach or in the event of bankruptcy, insolvency or similar proceedings of the other party.

Competitive tests and our advantages

Our T-SPOT.*TB* test competes primarily with the TST. In the United States, there are two brands of PPD for the TST: Aplisol[®] (manufactured by JHP Pharmaceuticals, Inc.)³ and Tubersol[®] (manufactured by Sanofi Pasteur Limited)⁴. Outside the United States, we believe the dominant brand worldwide is Tuberculin PPD RT 23 SSI (manufactured by the Statens Serum Institut, Denmark).

We believe our T-SPOT.*TB* test has a number of compelling advantages that make it a superior alternative to the 100-year-old TST, including:

- In head-to-head studies, our T-SPOT.*TB* test is frequently found to have higher sensitivity than the TST. In regulatory clinical trials (see “—Regulatory approvals and clinical validation”), we have demonstrated a sensitivity for the T-SPOT.*TB* test that exceeds 95%. In comparison, the TST is reported to have a sensitivity between 75-90% in similar populations. In addition, and unlike the TST, our T-SPOT.*TB* test is not significantly affected by immune suppression.
- Our T-SPOT.*TB* test is more specific than the TST, primarily because the antigens in our T-SPOT.*TB* test do not cross-react in individuals who have had the BCG vaccination or who have been infected with most other non-tuberculous mycobacteria.
- Our T-SPOT.*TB* test requires a simple blood draw, which does not require specifically trained healthcare workers to administer the test.
- There is no requirement for a return visit in 48 to 72 hours to obtain our T-SPOT.*TB* test result. This makes the testing process more convenient for patients and avoids the costs and inconvenience of readministering the test to those who fail to return to have the TST read.
- Our T-SPOT.*TB* test does not suffer from the “boosting” phenomenon that can affect the TST, as there is no injection of immunogenic substances into the body. Consequently, with our T-SPOT.*TB* test, two-step testing for new hires, which entails four visits, is not required and pre-hire screening can be condensed to a single visit.
- The combination of our T-SPOT.*TB* test’s greater accuracy and its logistical benefits means that the adoption of our T-SPOT.*TB* test can improve patient care while reducing costs for institutions.

The TST is often considered to be “cheap,” as the PPD reagent and other materials used in the test typically cost less than \$5 per test. However, the cost of the TST itself is only one element of the total cost involved when conducting a TB screening program or TB control strategy. Substantial costs beyond the materials cost of the TST test include additional costs associated with: (i) false-negatives and false-positives to the TST; (ii) individuals who fail to return within the prescribed period; and (iii) implementing and maintaining training programs for healthcare workers who administer and read TST tests.

Several studies have been published investigating the costs or cost-effectiveness of a TB screening program using the TST and in comparison to our T-SPOT.*TB* test. We believe the following studies are informative in demonstrating how expensive the TST actually is to implement and how deploying our T-SPOT.*TB* test in preference to the TST can be a more cost-effective solution when implementing TB screening programs.

- *Infection Control and Hospital Epidemiology* (Lambert et al., 2003). This CDC-led study sought to determine the annual costs of implementing and maintaining TST screening programs for healthcare workers at hospitals and health departments. The authors concluded that compliance with the CDC guidelines regarding TB infection control may require a substantial investment in personnel time, effort and commitment. The costs of running a TST program were found to be between \$41 and \$362 per healthcare worker for hospitals and between \$172 and \$264 per healthcare worker for health departments. The materials cost of the TST itself amounted to less than 1.5% of the total cost of the screening program in all the studied institutions.
- *Journal of Occupational and Environmental Medicine*: The SWITCH study (Wrighton-Smith et al., 2012). The SWITCH study, conducted at The Johns Hopkins Healthcare System and Medical School, was conceived to systematically identify and then measure all the costs of screening healthcare workers using either a TST or an IGRA (specifically, our T-SPOT.*TB* test). The key study findings were that administering a TST testing program costs \$73.20 per person screened, \$90.80 per new hire, and \$63.42 per annual screen. Use of an IGRA for employee health testing was found to be cost saving, with an IGRA test cost of \$54.83 or less per test, and to result in higher screening completion rates due to the elimination of the need for a second visit to interpret the TST. Dr. Peter Wrighton-Smith, our Chief Executive Officer, contributed as an author and scientific collaborator in this study.

³ Aplisol is a registered trademark of JHP Pharmaceuticals Inc.

⁴ Tubersol is a registered trademark of Sanofi Pasteur Limited.

[Table Of Contents](#)

- *Tuberculosis Screening of New Hospital Employees* (Foster-Chang et al., 2014). This study was conducted at an urban Veteran's Administration (VA) health care facility in Philadelphia, Pennsylvania, as part of a VA quality improvement investigation. The key study findings were that utilizing an IGRA (specifically, our T-SPOT.TB test) for new employee TB screening instead of the TST resulted in an average new employee clearance to work time of 5.91 days, as compared to 12.67 and 13.18 days during the 2011/2012 time frames, respectively, when utilizing the TST. Additionally, the authors reported a 38% to 40% reduction in cost for new employee TB screening when using the T-SPOT.TB test instead of the TST.

Other than the TST, our principal competitor is the QuantiFERON[®]5-TB Gold In-Tube test, or QFN. As this test also measures IFN- γ release, QFN, like our own test, is sometimes referred to generically as an IGRA.

We have been competing with QFN, or prior versions of this test, since the inception of our company. Based on our experience, we believe that we have several performance advantages over QFN, including:

- In our pivotal clinical trials conducted in the United States, our T-SPOT.TB test was shown to be unaffected by immunosuppression. The U.S. package insert for the QFN test notes that QFN has not been extensively evaluated in immunosuppressed populations and that indeterminate results may be related to immunosuppressed status of the patient. We believe this is an important differentiating factor in patient populations with weakened immune systems, such as those on biologic therapies, corticosteroid or other immunosuppressive treatments, those with HIV and those undergoing dialysis or organ transplantation.
- In the FDA pivotal trials in the United States, our T-SPOT.TB test was shown to have clinical sensitivity exceeding 95%. In the clinical trials for QFN reported in its U.S. package insert, that test was shown to have overall sensitivity of 89%. We believe this allows us to differentiate our test based on accuracy.
- Our test requires only a single tube of blood collected in a ubiquitous heparin blood tube. In contrast, QFN requires the use of three specialist antigen-coated blood collection tubes, either at the time of the blood draw or later. We believe this gives us a reliability and simplicity advantage.
- By using the T-Cell *Xtend* reagent with our T-SPOT.TB test, we have up to 32 hours to get a blood sample to a processing laboratory, as compared with QFN where blood must be incubated within 16 hours. We believe this significant time advantage gives our test greater flexibility over blood collection windows, as the processing of the blood is less time critical. Our test also allows for the overnight shipment of blood samples without imposing additional processing steps on the customer.

In addition to the performance advantages we believe we have over QFN, we have developed and implemented the ability to offer our test as a service in the United States and the United Kingdom. The advantages of offering our test as a service include:

- We are in direct contact with the individuals and organizations ordering our test via our ODL service offering. We believe this level of direct engagement provides us market insights and marketing opportunities not available to the manufacturer of QFN.
- Our test's availability is not limited by whether or not a suitable laboratory exists local to the customer. As a result, we believe we can offer testing with more convenient access times to a more diverse set of customers.
- We offer our customers access to our laboratory service seven days a week.
- We offer a rapid and consistent test turnaround time, which we believe is typically faster than that offered by other laboratories running QFN.
- Our ODL customers require minimal set-up and training in order to access the test because our service allows our customers to package the test samples in our pre-paid shipper boxes. This development reduces on-boarding time and maximizes simplicity for the customer.
- We are well positioned to offer additional services to our customers over and above providing a test result. We believe that this advantage allows us the ability to generate additional revenue and increase switching costs for customers.

As a result of clinical and service advantages, we have been able to negotiate a higher average selling price for our service. We believe this advantage provides us a larger addressable market than is available through selling kits as done by QFN; simply put our revenue potential from the same testing volume is higher. We believe that this will also enable us to achieve a higher absolute profit per test. However, to the extent that national and regional laboratories offer QFN as a service, we may also face competition from them in our service offering.

The benchmark reimbursement for our T-SPOT.TB test is higher than for QFN in the United States, with CMS reimbursement of \$102 per test for CPT code 86481 as opposed to CMS reimbursement of \$84 per test for CPT code 86480. We believe that this higher reimbursement provides us with pricing and access advantages in certain segments of the U.S. market.

In early 2015, a new version of QFN, the QuantiFERON-TB gold Plus test (QFN Plus), was announced in the European Union. Based on the data presented in their respective package inserts, QFN Plus has a higher clinical sensitivity (95.3%) but lower clinical specificity (97.6%) than QFN. No independent verification of this data is currently available. QFN Plus also requires the use of a fourth specialist antigen-coated blood collection tube, either at the time of blood draw or later. QFN Plus is not available in the United States.

⁵ QuantiFERON is a registered trademark of Qiagen N.V.

Government regulation

Federal Food, Drug, and Cosmetic Act

In the United States, *in vitro* diagnostics are regulated by the FDA as medical devices under the Federal Food, Drug, and Cosmetic Act, or FDCA.

Marketing pathways

There are two regulatory pathways to receive authorization to market *in vitro* diagnostic devices, or IVDs: a 510(k) premarket notification and a PMA. The FDCA establishes a risk-based standards for determination the pathway for which a particular IVD device is eligible.

The information that must be submitted to the FDA to obtain clearance or approval to market a new medical device varies depending on how the medical device is classified by the FDA. Medical devices are classified into one of three classes on the basis of the controls necessary to reasonably ensure their safety and effectiveness. Class I devices are subject to general controls, including labeling and adherence to the FDA's quality system regulation, which establishes device-specific good manufacturing practices. Class II devices are subject to general controls and special controls, including performance standards and post-market surveillance. Class III devices are subject to these requirements as well as to premarket approval. Most Class I devices are exempt from premarket submissions to the FDA; most Class II devices require the submission of a 510(k) premarket notification to the FDA; and Class III devices require submission of a PMA application. Our T-SPOT.*TB* test is a Class III device.

Premarket approval. The PMA process, by which we received marketing authorization for our T-SPOT.*TB* test in 2008, is complex, costly and time consuming. A PMA application must be supported by detailed and comprehensive scientific evidence, including clinical data, to demonstrate the safety and efficacy of the medical device for its intended purpose. If the device is determined to present a "significant risk," the sponsor may not begin a clinical trial until it submits an investigational device exemption, or IDE, to the FDA and obtains approval from the FDA to begin the trial. After the PMA application is submitted, the FDA has 45 days to make a threshold determination that the application is sufficiently complete to permit a substantive review. If the application is complete, the FDA will accept it for filing. The FDA is subject to a non-binding performance goal review time for a PMA application of 180 days from the date of filing, although in practice this review time is often longer. Questions from the FDA, requests for additional data and referrals to advisory committees may delay the process considerably. Indeed, the total process may take several years and there is no guarantee that the PMA application will ever be approved. Even if approved, the FDA may limit the indications for which the device may be marketed. The FDA may also request additional clinical data as a condition of approval or after the PMA is issued. Any changes to the medical device may require a supplemental PMA application to be submitted and approved. Since we received initial PMA application approval of our T-SPOT.*TB* test in 2008, the FDA has granted approval for ten supplemental PMA applications for our T-SPOT.*TB* test, including supplements relating to the use of our T-Cell *Xtend* reagent with our T-SPOT.*TB* test.

510(k) Clearance. A traditional 510(k) submission requires demonstration of substantial equivalence to a previous legally marketed device that was not subject to PMA. If a substantial equivalence cannot be demonstrated and the test is of low to moderate risk, the FDA may allow a *de novo* 510(k) submission. Submission of either a traditional or *de novo* 510(k) notification is subject to a 90-day FDA review period. Questions from the FDA, requests for additional data and referrals to advisory committees may delay the process considerably and the FDA may ultimately limit the indications for which the device may be marketed. Marketing of an IVD medical device may begin as soon as FDA clearance is granted.

FDA Guidance on LDTs. The FDA has historically exercised enforcement discretion over the regulation of LDTs. In October 2014, the FDA issued draft guidance for the oversight of LDTs that included notification and medical device reporting. Under the draft guidance, the FDA will classify LDTs as high, medium or low risk tests, which will then dictate the regulatory route to be followed for each test. The draft guidance states that existing LDTs will be allowed to remain on the market during completion of the regulatory process. The draft guidance indicates that the regulatory requirements would begin twelve months after issuance of final guidance, with phase in over four years for high risk tests. Enforcement for moderate risk tests would begin five years after issuance of the final guidance. It is uncertain whether the final guidance will retain these requirements and when such final guidance may issue.

Post-marketing regulations and controls

Under the medical device regulations, the FDA regulates quality control and manufacturing procedures by requiring us to demonstrate and maintain compliance with the quality system regulation, which sets forth the FDA's current good manufacturing practices requirements for medical devices. The FDA monitors compliance with the quality system regulation and current good manufacturing practices requirements by conducting periodic inspections of manufacturing facilities. FDA inspections in the United States are typically unannounced. FDA inspections outside the United States are coordinated with the companies being inspected. Violations of applicable regulations noted by the FDA during inspections of our manufacturing facilities could adversely affect the continued marketing of our tests.

[Table Of Contents](#)

The FDA also enforces post-marketing controls that include the requirement to submit medical device reports to the agency when a manufacturer becomes aware of information suggesting that any of its marketed products may have caused or contributed to a death, serious injury or serious illness or any of its products has malfunctioned and that a recurrence of a malfunction would likely cause or contribute to a death or serious injury or illness. The FDA relies on medical device reports to identify product problems and utilizes these reports to determine, among other things, whether it should exercise its enforcement powers. The FDA also enforces the requirement that manufacturers submit reports of recalls and field actions to the FDA if the actions are initiated to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health. The FDA may also require post-market surveillance studies for specified devices.

FDA regulations also govern, among other things, the preclinical and clinical testing, manufacture, distribution, labeling and promotion of medical devices. In addition to compliance with good manufacturing practices and medical device reporting requirements, we are required to comply with the FDCA's general controls, including establishment registration, device listing and labeling requirements. If we fail to comply with any requirements under the FDCA, we could be subject to, among other things, fines, injunctions, civil penalties, recalls or product corrections, total or partial suspension of production, denial of premarket notification clearance or approval of products, rescission or withdrawal of clearances and approvals, and criminal prosecution. We cannot assure you that any final FDA policy, once issued, or future laws and regulations concerning the manufacture or marketing of medical devices will not increase the cost and time to market of new or existing tests. If we fail to comply with these FDA regulations or guidelines, we may be subject to warnings from, or enforcement action by, the FDA.

International medical device regulations

International marketing of medical devices is subject to foreign government regulations, which vary substantially from country to country. The European Commission is the legislative body responsible for directives with which manufacturers selling medical products in the European Union and the European Economic Area, or EEA, must comply. The European Union includes most of the major countries in Europe, while other countries, such as Switzerland, are part of the EEA and have voluntarily adopted laws and regulations that mirror those of the European Union with respect to medical devices. The European Union has adopted directives that address regulation of the design, manufacture, labeling, clinical studies and post-market vigilance for medical devices, including IVDs. Devices that comply with the requirements of a relevant directive, including the IVD Directive (Directive 98/79 EC), will be entitled to bear the CE conformity marking, indicating that the device conforms to the essential requirements of the applicable directives and, accordingly, can be marketed throughout the European Union and EEA.

Outside of the European Union, regulatory pathways for the marketing of medical devices vary greatly from country to country. In many countries, local regulatory agencies conduct an independent review of IVD medical devices prior to granting marketing approval. For example, in China, approval by the CFDA, must be obtained prior to marketing an IVD medical device. In Japan, approval by the MHLW following review by the Pharmaceuticals and Medical Devices Agency, or the PMDA is required prior to marketing an IVD. The process in such countries may be lengthy and require the expenditure of significant resources, including the conduct of clinical trials. In other countries, the regulatory pathway may be shorter and/or less costly. The timeline for the introduction of new IVD medical devices is heavily impacted by these various regulations on a country-by-country basis, which may become more lengthy and costly over time.

Our T-SPOT.*TB* test has been approved for sale in over 50 countries, including in Europe, China, and Japan. Our T-SPOT.*TB* test obtained a CE mark in 2004, CFDA approval in China in 2010 and re-registration in 2014, and MHLW approval in Japan in 2012.

Laboratory certification, accreditation and licensing

As a company engaged in the diagnostic testing business, we are required to maintain certain federal and state licenses, certificates and permits.

United States. In the United States, Clinical Laboratories Improvement Amendments of 1988, or CLIA, imposes requirements relating to test processes, personnel qualifications, facilities and equipment, record keeping, quality assurance and participation in proficiency testing, which involves comparing the results of tests on specimens that have been specifically prepared for our laboratory to the known results of the specimens. The CLIA requirements also apply as a condition for participation by clinical laboratories under the Medicare program. Under the CLIA regulations, the complexity of the tests performed determines the level of regulatory control. United States Department of Health and Human Services, or HHS, classifies our T-SPOT.*TB* test as a high-complexity test. As a result, we must employ more experienced and highly educated personnel, as well as additional categories of employees.

HHS, or an organization to which HHS delegates authority, verifies compliance with CLIA standards through periodic on-site inspections. Sanctions for failure to meet these certification, accreditation and licensure requirements include suspension or revocation of the certification, accreditation or license, as well as imposition of plans to correct deficiencies, injunctive actions and civil and criminal penalties. If HHS should remove or suspend our CLIA certificate, we would be forced to cease performing testing at our laboratory in Memphis, Tennessee.

[Table Of Contents](#)

We are also accredited by the College of American Pathologists, or CAP. The CAP Laboratory Accreditation Program is an internationally recognized program that utilizes teams of practicing laboratory professionals as inspectors, and accreditation by CAP can often be used to meet CLIA and state certification requirements.

United Kingdom. Our laboratory located in the United Kingdom operates under accreditation by the United Kingdom Accreditation Service, or UKAS, for the International Standard: ISO 17025:2005 (General requirements for the competence of testing and calibration laboratories). Compliance with this standard is required to maintain accreditation and the continued use of the UKAS logo on our laboratory documentation. National Health Service (NHS)-based customers require that the testing services they procure operate to an accredited quality management system, which is evidenced by the UKAS accreditation. Therefore, a failure to maintain this accreditation could cause us to lose a substantial majority of our U.K. service business.

HIPAA and other privacy laws

U.S. Health Insurance Portability and Accountability Act, or HIPAA, established for the first time in the United States comprehensive protection for the privacy and security of health information. The HIPAA standards apply to three types of organizations, or Covered Entities: health plans, healthcare clearing houses, and healthcare providers that conduct certain healthcare transactions electronically. Covered Entities and their Business Associates, as defined in HIPAA, must have in place administrative, physical, and technical standards to guard against the misuse of individually identifiable health information. Because we are a healthcare provider and we conduct certain healthcare transactions electronically, we are currently a Covered Entity, and we must have in place the administrative, physical, and technical safeguards required by HIPAA, the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations. Additionally, some state laws impose privacy protections more stringent than HIPAA. We may conduct other activities that may implicate HIPAA, such as conducting clinical studies or entering into specific kinds of relationships with a Covered Entity or a Business Associate of a Covered Entity.

If we or our operations are found to be in violation of HIPAA, HITECH or their implementing regulations, we may be subject to penalties, including civil and criminal penalties, fines, and exclusion from participation in U.S. federal or state health care programs, and the curtailment or restructuring of our operations. HITECH increased the civil and criminal penalties that may be imposed against Covered Entities, their Business Associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions.

Our activities must also comply with other applicable privacy laws. For example, there are also international privacy laws that impose restrictions on the access, use, and disclosure of health information. All of these laws may impact our business. Our failure to comply with these privacy laws or significant changes in the laws could significantly impact our business and our future plans.

U.S. federal and state billing and fraud and abuse laws

Although only a small portion of our U.S. diagnostics business currently involves payment by third-party payors, including government payors, we are subject to numerous laws governing billing for health care services.

Antifraud laws / overpayments. As participants in federal and state healthcare programs, we are subject to numerous federal and state anti-fraud and abuse laws. Prohibitions under some of these laws include:

- the submission of false claims or false information to government programs;
- deceptive or fraudulent conduct;
- excessive or unnecessary services or services at excessive prices; and
- defrauding private sector health insurers.

We could be subject to substantial penalties for violations of these laws, including denial of payment, obligation to issue refunds, suspension of payments from Medicare, Medicaid or other federal healthcare programs and exclusion from participation in the federal healthcare programs, as well as civil and criminal penalties and imprisonment. One of these statutes, the False Claims Act, is a key enforcement tool used by the government to combat healthcare fraud.

Numerous federal and state agencies enforce anti-fraud and abuse laws. In addition, private insurers may bring private actions. In some circumstances, private whistleblowers are authorized to bring fraud suits on behalf of the government against providers and are entitled to receive a portion of any final recovery.

U.S. federal and state "anti-kickback" and "self-referral" restrictions

Anti-kickback statute. The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending, or arranging for a good or service, for which payment may be made under a federal healthcare program, such as the Medicare and Medicaid programs. The term "remuneration" is not defined in the federal Anti-Kickback Statute and has been broadly interpreted to include anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payment, ownership interests and providing anything at less than its fair market value.

[Table Of Contents](#)

Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs, and do not contain identical safe harbors.

If we or our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in U.S. federal or state health care programs, and the curtailment or restructuring of our operations. We may also be subject to similar foreign laws and regulations.

Self-referral law. We are subject to a federal “self-referral” law, commonly referred to as the “Stark” law, which provides, unless a specific exception applies, that physicians who, personally or through a family member, have ownership interests in or compensation arrangements with a laboratory are prohibited from making a referral to that laboratory for laboratory tests reimbursable by Medicare, and also prohibits laboratories from submitting a claim for Medicare payments for laboratory tests referred by physicians who, personally or through a family member, have ownership interests in or compensation arrangements with the testing laboratory.

We are subject to comparable state laws, some of which apply to all payors regardless of source of payment, and do not contain identical exceptions to the Stark law. The self-referral laws may cause some physicians who would otherwise use our laboratory to use other laboratories for their testing. Providers are subject to sanctions for claims submitted for each service that is furnished based on a referral prohibited under the federal self-referral laws. These sanctions include denial of payment, obligation to issue refunds, civil monetary payments and exclusion from participation in federal healthcare programs and civil monetary penalties. They may also include penalties for applicable violations of the False Claims Act, which may require payment of up to three times the actual damages sustained by the government, plus civil penalties of up to \$5,500 to \$11,000 for each separate false claim.

U.S. health care reform

In March 2010, the Patient Protection and Affordable Care Act of 2010, as amended by the Healthcare and Education Affordability Reconciliation Act of 2010, or the PPACA, was enacted, which includes measures that have or will significantly change the way healthcare is financed by both governmental and private insurers. The Physician Payment Sunshine Act, enacted as part of PPACA, and its implementing regulations require medical device manufacturers to track certain financial arrangements with physicians and teaching hospitals, including any “transfer of value” made or distributed to such entities, as well as any investment interests held by physicians and their immediate family members. Manufacturers are required to report this information to CMS. Various states have also implemented regulations prohibiting certain financial interactions with healthcare professionals and/or mandating public disclosure of such financial interactions. We may incur significant costs to comply with such laws and regulations now or in the future.

Other laws

We are also subject to numerous U.S. federal, state and local laws as well as international laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and transportation and disposal of blood and hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future.

Employees

As of December 31, 2014, we had 240 employees. None of our employees is represented by a labor union. However, we have one employee in Belgium covered under a collective bargaining agreement. We have not experienced any work stoppages and we believe our employee relations are good.

Environmental matters

Our operations require the use of hazardous materials, which, among other matters, subjects us to a variety of federal, state, local and foreign environmental, health and safety laws, regulations and permitting requirements, including those relating to the handling, storage, transportation and disposal of biological and hazardous materials and wastes. The primary hazardous materials we handle or use include human blood samples and solvents. Some of the regulations under the current regulatory structure provide for strict liability, holding a party liable for contamination at currently and formerly owned, leased and operated sites and at third-party sites without regard to fault or negligence. We could be held liable for damages and fines as a result of our, or others', operations or activities should contamination of the environment or individual exposure to hazardous substances occur. We could also be subject to significant fines for failure to comply with applicable environmental, health and safety requirements. We cannot predict how changes in laws or development of new regulations will affect our business operations or the cost of compliance.

Available Information

Access to our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to these reports filed with or furnished to the Securities and Exchange Commission, or SEC, may be obtained through the investor section of our website at www.oxfordimmunotec.com as soon as reasonably practical after we electronically file or furnish these reports. We do not charge for access to and viewing of these reports. Information in the investor section and on our website is not part of this Annual Report on Form 10-K or any of our other securities filings unless specifically incorporated herein by reference. In addition, the public may read and copy any materials that we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Also, our filings with the SEC may be accessed through the SEC's website at www.sec.gov. All statements made in any of our securities filings, including all forward-looking statements or information, are made as of the date of the document in which the statement is included, and we do not assume or undertake any obligation to update any of those statements or documents unless we are required to do so by law.

Corporate information

Oxford Immunotec Global PLC was incorporated in England and Wales in 2013. On October 2, 2013, we completed a scheme of arrangement under the laws of England and Wales, or the Scheme of Arrangement, pursuant to which equity holders exchanged their equity interests in Oxford Immunotec Limited for equity interests in Oxford Immunotec Global PLC. Prior to the Scheme of Arrangement, our business was conducted by Oxford Immunotec Limited and its consolidated subsidiaries. Oxford Immunotec Limited, a private limited company, was incorporated in England and Wales in 2002. Following the Scheme of Arrangement, our business has been conducted by Oxford Immunotec Global PLC and its consolidated subsidiaries, including Oxford Immunotec Limited. Our principal executive offices are located at 94C Innovation Drive, Milton Park, Abingdon, OX14 4RZ, United Kingdom, and our telephone number is +44 (0) 1235 442 780. Our internet website is www.oxfordimmunotec.com. The information on, or that can be accessed through, our website is not part of this Annual Report on Form 10-K.

Item 1A. Risk Factors

Risks related to our business.

We have a history of losses and anticipate that we will incur continued losses for at least the next few years. We cannot be certain that we will achieve or sustain profitability.

We were founded in 2002 and to date we have engaged primarily in development, clinical testing and marketing of our T-SPOT.TB test. We have never been profitable. For the fiscal years ended December 31, 2014, 2013, and 2012, we had net losses of \$22.2 million, \$8.7 million, and \$14.9 million, respectively, and we had an accumulated deficit at December 31, 2014 of \$121.8 million. Substantially all of our operating losses in these periods resulted from costs incurred in connection with sales and marketing of our T-SPOT.TB test, general and administrative costs associated with our operations and our research and development programs. Even though we generate revenue from our T-SPOT.TB test, we anticipate that our operating losses will continue for the next few years as we continue to invest to grow our customer base and invest in research and development to expand our product portfolio. Because of the numerous risks and uncertainties associated with developing and commercializing diagnostic products, we are unable to predict the magnitude of these future losses. Our historic losses, combined with expected future losses, have had and will continue to have an adverse effect on our cash resources, shareholders' deficit and working capital. We expect our research and development expenses to be substantial for at least the next few years as we work to develop other product candidates based on our T-SPOT technology.

Our ability to become profitable depends upon our ability to generate revenue. In 2004, we began to generate revenue from the sale and marketing of our T-SPOT.TB test, but we may not be able to generate sufficient revenue to attain profitability. Our ability to generate profits on sales of our T-SPOT.TB test is subject to market acceptance in market segments we currently serve as well as in new market segments and new geographies. In addition, we may be compelled to sell our T-SPOT.TB test at lower prices if, for example, our customers or prospective customers are unwilling to pay for our tests at current pricing levels or as a result of increased competition generally. Any price erosion would impede our ability to generate revenue. If we are unable to generate sufficient revenue, we will not become profitable and may be unable to continue operations without continued funding.

We are currently heavily dependent on the successful further commercialization of our T-SPOT.TB test and, if we encounter delays or difficulties in the further commercialization of this product, our business could be harmed.

Our future success is heavily dependent upon the successful further commercialization of our T-SPOT.TB test. There is no assurance that we will continue to generate revenues from this product, or any products under development, in the future. Our business could be materially harmed if we encounter difficulties in the further commercialization of this product, including, among others: failure to achieve sufficient market acceptance by hospitals and public health departments as well as physicians, third-party payors and others in the medical community; the inability to compete with other diagnostic methods, including the TST; the inability to maintain and expand our sales, marketing and distribution networks; the inability to manage anticipated growth; the inability to obtain and/or maintain necessary regulatory approvals; and the inability to effectively protect our intellectual property.

Our financial results will depend on the market acceptance and increased demand of our products by hospitals and public health departments, as well as physicians and others in the medical community.

Our future success depends on our products test gaining sufficient market acceptance by hospitals and public health departments. If this product does not achieve an adequate level of acceptance by such customer groups, we may not generate enough revenue to become profitable. The degree of market acceptance of our products test will depend on a number of factors, including:

- clinical guidelines relative to the screening for, and diagnosis and monitoring of, TB infection;
- the efficacy and potential advantages of our T-SPOT.TB test over alternative tests;
- the willingness of our target customers to accept and adopt our T-SPOT.TB test;
- the ability to offer attractive pricing for our T-SPOT.TB test;
- the strength of marketing and distribution support and the timing of market introduction of competitive products; and
- outcomes from clinical studies and other publicity concerning our T-SPOT.TB test or competing products.

Our efforts to educate physicians and other members of the medical community on the benefits of our T-SPOT.TB test may require significant resources and may never be successful. Such efforts to educate the marketplace may require more resources than are required by conventional technologies marketed by our competitors. In particular, continuing to gain market acceptance for our T-SPOT.TB test in nascent markets could be challenging. In certain markets, including, for example, Japan and China, our potential for future growth is difficult to forecast. If we were to incorrectly forecast our ability to penetrate these markets, expenditures that we make may not result in the benefits that we expect, which could harm our results of operations. Moreover, in the event that our T-SPOT.TB test is the subject of guidelines, clinical studies or scientific publications that are unhelpful or damaging, or otherwise call into question the benefits of our T-SPOT.TB test, we may have difficulty in convincing prospective customers to adopt our test. Moreover, the perception by the investment community or shareholders that recommendations, guidelines or studies will result in decreased use of our products could adversely affect the prevailing market price for our ordinary shares.

The success of our T-SPOT.TB test depends on the continued demand for diagnostic products for tuberculosis.

Even if we achieve market acceptance, our success will depend on continued demand for diagnostic products for tuberculosis. Tuberculosis screening policies could change such that tests are conducted less frequently or in fewer instances. For example, healthcare institutions facing increased cost control requirements could determine to reduce employee testing. In addition, various institutions or governing bodies may decide that the incidence of TB has dropped sufficiently within their screening population so as to permit reduced testing (e.g., U.S. military guidelines were recently updated such that testing may now be required in fewer instances than under previous guidelines). If there are widespread testing policy changes that substantially reduce testing in the markets we serve, our business could be materially and adversely affected.

New market opportunities may not develop as quickly as we expect, limiting our ability to market and sell our T-SPOT.TB test successfully.

We intend to take steps to continue to increase the presence of our T-SPOT.TB test in new markets both in the United States and internationally. We intend to expand our sales force globally and establish additional distributor relationships outside of our direct markets to better access international markets. We believe these opportunities will take substantial time to develop or mature, however, and we cannot be certain that these market opportunities will develop as we expect. The future growth and success of our T-SPOT.TB test in these markets depends on many factors beyond our control, including recognition and acceptance by the scientific community in that market and the prevalence and costs of competing methods of tuberculosis screening. If the markets for our T-SPOT.TB test do not develop as we expect, our business may be adversely affected.

Our T-SPOT.TB test competes with other diagnostic testing methods that may be more widely accepted than our test, and may compete with new diagnostic tests that may be developed by others in the future, which could impair our ability to maintain and grow our business and remain competitive.

The clinical diagnostics market is highly competitive, and we must be able to compete effectively against existing and future competitors in order to be successful. In selling our T-SPOT.TB test, we compete primarily with existing diagnostic technologies, particularly the TST, which is widely used as a test for diagnosing tuberculosis. In addition, we compete with QFN which, like our T-SPOT.TB test, employs an interferon-gamma release assay, or IGRA, method for diagnosing tuberculosis. If we are unable to differentiate our diagnostic tests from those of our competitors, our business may be materially and adversely affected. In addition, improvements in these technologies or the development of new technologies for diagnosing tuberculosis and the introduction of products that compete with our T-SPOT.TB test could adversely impact our ability to sell our T-SPOT.TB test or the sales price of the test. This could impact our ability to market our test and/or secure a distribution partner, both of which could have a substantial impact on the value of our T-SPOT.TB test.

We also face competition in the development, manufacture, marketing and commercialization of diagnostic products from a variety of other sources, such as academic institutions, government agencies, research institutions and other life sciences companies. These competitors are working to develop and market other diagnostic tests, systems, products and other methods of detecting, preventing or reducing tuberculosis.

[Table Of Contents](#)

Among the many experimental diagnostics being developed around the world, there may be diagnostics unknown to us that may compete with our T-SPOT.*TB* test. Many of our potential competitors have much greater capital resources, manufacturing, research and development resources and production facilities than we do. Competitors with greater resources may be able to offer tests and/or services at prices at which we are unable to compete and more quickly develop improvements than we are. Many of them may also have more experience than we have in preclinical testing and clinical trials of new diagnostic tests.

In our service offering, we also may face competition from commercial laboratories, including large national and regional laboratories, which may be able to offer access to TB testing. These laboratories may have perceived advantages over our solution, including phlebotomy services, established payor relationships and dedicated courier services. For example, as we seek to further penetrate the physicians' office segment of the U.S. market, we may find that physicians have established relationships with commercial laboratories that offer physicians additional services, such as phlebotomy, and a wider range of available laboratory tests that a physician may choose to order in addition to a TB test. Further, some commercial laboratories may be able to offer their services at lower cost to physicians' patients due to the reimbursement arrangements these laboratories may have established with third-party payors. These factors may make it difficult for us to convince physicians to use our test and service offering.

The markets for our T-SPOT.*TB* test are subject to changing technology, new product introductions and product enhancements, and evolving industry standards. The introduction or enhancement of products embodying new technology or the emergence of new industry standards could render existing products obsolete or result in short product life cycles or our inability to sell our T-SPOT.*TB* test without offering a significant discount.

If we are unable to maintain and expand our network of direct sales representatives and independent distributors, we may not be able to generate anticipated sales.

We sell our T-SPOT.*TB* test through our own sales force in the United States, certain European countries and Japan and we sell through distributors in other parts of the world such as in China. Our operating results are directly dependent upon the sales and marketing efforts of not only our employees, but also our independent distributors. We expect our direct sales representatives and independent distributors to develop long-lasting relationships with the providers they serve. If our direct sales representatives or independent distributors fail to adequately promote, market and sell our product, our sales could significantly decrease.

We face significant challenges and risks in managing our geographically dispersed sales and distribution network and retaining the individuals who make up that network. If a substantial number of our direct sales representatives were to leave us within a short period of time, or if a substantial number of our independent distributors were to cease to do business with us within a short period of time, our sales could be adversely affected. If any significant independent distributor were to cease to distribute our product, our sales could be adversely affected. In such a situation, we may need to seek alternative independent distributors or increase our reliance on our direct sales representatives, which may not prevent our sales from being adversely affected. If a direct sales representative or independent distributor were to depart and be retained by one of our competitors, we may be unable to prevent them from helping competitors solicit business from our existing customers, which could further adversely affect our sales. Because of the intense competition for their services, we may be unable to recruit additional qualified independent distributors or to hire additional qualified direct sales representatives to work with us. We may also not be able to enter into agreements with them on favorable or commercially reasonable terms, if at all. Failure to hire or retain qualified direct sales representatives or independent distributors would prevent us from expanding our business and generating sales. See "—Certain of our customers account for a significant portion of our revenue."

As we launch new products and increase our sales, marketing and distribution efforts with respect to our T-SPOT.*TB* test, we will need to expand the reach of our sales, marketing and distribution networks. Our future success will depend largely on our ability to continue to hire, train, retain and motivate skilled direct sales representatives and independent distributors with significant technical knowledge in various areas. New hires require training and take time to achieve full productivity. If we fail to train new hires adequately, or if we experience high turnover in our sales force in the future, we cannot be certain that new hires will become as productive as may be necessary to maintain or increase our sales.

If we are unable to expand our sales and marketing capabilities domestically and internationally, we may not be able to effectively commercialize our product, which would adversely affect our business, results of operations and financial condition.

Health insurers and other payors may decide not to cover, or may discontinue reimbursing, our T-SPOT.*TB* test or any other diagnostic tests we may develop in the future, or may provide inadequate reimbursement, which could jeopardize our ability to expand our business.

Although for many of our current customers, including those in the hospital and public health segments, the cost of screening their employees for tuberculosis is not reimbursable, our business is somewhat impacted, and in the future may be more greatly impacted, by the level of reimbursement from payors or governmental limitations on price. In the United States, the regulatory process allows diagnostic tests to be marketed regardless of any coverage determinations made by payors. For new diagnostic tests, each payor makes its own decision about which tests it will cover, how much it will pay and whether it will continue reimbursing the test. Clinicians may order diagnostic tests that are not reimbursed if the patient is willing to pay for the test without reimbursement, but coverage determinations and reimbursement levels and conditions are important to the commercial success of a diagnostic product. In addition, eligibility for coverage does not imply that any product will be covered and reimbursed in all cases or reimbursed at a rate that allows our potential customers to make a profit or even cover their costs.

[Table Of Contents](#)

CMS establishes reimbursement payment levels and coverage rules for Medicare. CMS currently covers our T-SPOT.*TB* test. If CMS were to place significant restrictions on the use of our tests, reduce payment amounts or eliminate coverage altogether, our ability to generate revenue from our diagnostic tests could be limited. For example, payment for diagnostic tests furnished to Medicare beneficiaries is made based on a fee schedule set by CMS. In July 2013, CMS released certain proposals that re-examined payment amounts for tests reimbursed under the Medicare clinical laboratory fee schedule due to changes in technology. CMS also proposed to bundle the Medicare payments for certain laboratory tests ordered while a patient received services in a hospital outpatient setting, replacing the current methodology to make separate payments for the test. These changes went into effect on January 1, 2014. In addition, payment methodologies may be subject to changes in healthcare legislation. In February 2012, President Obama signed the Middle Class Tax Relief and Job Creation Act of 2012, which mandated an additional change in reimbursement for clinical laboratory services payments. This legislation required CMS to reduce the Medicare clinical laboratory fee schedule by 2% in 2013, which in turn serves as the base for 2014 and subsequent years. Levels of reimbursement may continue to decrease in the future, and future legislation, regulation or reimbursement policies of third-party payors may harm the demand and reimbursement available for our T-SPOT.*TB* test, which in turn, could harm our product pricing and sales. If our customers are not adequately reimbursed for our T-SPOT.*TB* test, they may reduce or discontinue purchases of our product, which would cause our revenues to decline.

In addition, state Medicaid plans and private commercial payors establish rates and coverage rules independently. As a result, the coverage determination process is often a time-consuming and costly process that requires us to provide scientific and clinical support for the use of our tests to each payor separately, with no assurance that coverage or adequate reimbursement will be obtained. Even if one or more third-party payors decides to reimburse for our tests, that payor may reduce utilization or stop or lower payment at any time, which could reduce our revenue. We cannot predict whether or when third-party payors will cover our tests or offer adequate reimbursement to make them commercially attractive. Clinicians may decide not to order our tests if inadequate third-party payments result in additional costs to the patient.

We are also subject to foreign reimbursement and payment schemes in the international markets we serve, including Germany, Switzerland, France, Japan and China. Decisions by health insurers or other third-party payors in these markets not to cover, or to discontinue reimbursement, or governmental limitations on price could materially and adversely affect our business.

Billing complexities associated with obtaining payment or reimbursement for our tests may negatively affect our revenue, cash flow and profitability.

Although third-party payors accounted for only 3% of our total revenue for the year ended December 31, 2014, we currently rely in part, and may in the future more heavily rely, on obtaining third-party payment or reimbursement for our test. We or our customers receive payment from individual patients and from a variety of payors, such as commercial insurance carriers, including managed care organizations and governmental programs, primarily Medicare and Medicaid in the United States. Each payor typically has different billing requirements, and the billing requirements of many payors have become increasingly stringent.

Among the factors complicating our billing of, and obtaining payment through, third-party payors are:

- disputes among payors as to which party is responsible for payment;
- disparity in coverage among various payors;
- disparity in information and billing requirements among payors;
- incorrect or missing billing information, which is required to be provided by the ordering physician; and
- payments may be sent directly to patients rather than to us.

These billing complexities, and the related uncertainty in obtaining payment for our tests, could negatively affect our revenue, cash flow and profitability.

If we do not achieve, sustain or successfully manage our anticipated growth, our business and financial results may be adversely affected.

We have experienced significant revenue growth in a relatively short period of time. We may not achieve similar growth rates in future periods. Investors should not rely on our operating results for any prior periods as an indication of our future operating performance. If we are unable to maintain adequate revenue growth, our financial results could suffer and our share price could decline.

Further development and commercialization of our T-SPOT.*TB* test and other diagnostic product candidates will require us to expand our sales, marketing and distribution networks. Such growth may place significant strains on our management and our internal systems and processes, as well as potentially those of our suppliers, and if we cannot effectively manage expanding operations and costs, we may not be able to continue to grow or we may grow at a slower pace and our business and financial results could be adversely affected.

We depend upon a limited number of suppliers, and certain components of our product may only be available from a sole source or limited number of suppliers.

Our T-SPOT.TB test is generally assembled by us from supplies we obtain from a limited number of suppliers. Critical components required to assemble our tests may only be available from a sole or limited number of component suppliers. For example, we source key components of our T-SPOT.TB test from EMD Millipore Corporation, Stemcell Technologies Inc., Mabtech AB, MicroCoat Biotechnologie GmbH and Life Technologies Corporation, any of whom would be difficult to replace. Even if the key components that we source are available from other parties, the time and effort involved in obtaining any necessary regulatory approvals for substitutes could impede our ability to replace such components timely or at all. The loss of a sole or key supplier would impair our ability to deliver products to our customers in a timely manner and would adversely affect our sales and operating results and negatively impact our reputation. Our business would also be harmed if any of our suppliers could not meet our quality and performance specifications and quantity and delivery requirements.

Certain of our customers account for a significant portion of our revenue.

We sell our T-SPOT.TB test through a direct sales force in the United States, certain European countries and Japan. In Japan, while we maintain end-user relationships through our direct sales force, we sell through a single importer of record, Riken. In other parts of the world, we sell through distributors. For example, in China, we sell through a single distributor, Fosun. For the year ended December 31, 2014, sales to Fosun and through Riken together accounted for 31% of our total revenue, with Fosun accounting for 17% and Riken accounting for 14%. In the event that either of these customers or any other significant customer substantially reduces its purchases of our products, particularly if this occurs without adequate advance notice to enable us to secure alternate importation or distribution arrangements, our results of operations could be materially and adversely affected.

We or our suppliers may experience development or manufacturing problems or delays that could limit the growth of our revenue or increase our losses.

We may encounter unforeseen situations in the manufacture and assembly of our T-SPOT.TB test that would result in delays or shortfalls in our production. Our suppliers may also face similar delays or shortfalls. In addition, our or our suppliers' production processes and assembly methods may have to change to accommodate any significant future expansion of our manufacturing capacity, which may increase our or our suppliers' manufacturing costs, delay production of our product, reduce our product margin and adversely impact our business. If we are unable to keep up with demand for our product by successfully manufacturing and shipping our product in a timely manner, our revenue could be impaired, market acceptance for our product could be adversely affected and our customers might instead purchase our competitors' products. In addition, developing manufacturing procedures for new products would require developing specific production processes for those products. Developing such processes could be time consuming, and any unexpected difficulty in doing so can delay the introduction of a product.

We currently perform our tests for our service offering exclusively in one laboratory facility in the United States and one laboratory in the United Kingdom. If these or any future facilities or our equipment were damaged or destroyed, or if we experience a significant disruption in our operations for any reason, our ability to continue to operate our business could be materially harmed.

We currently perform our T-SPOT.TB test for our service offering in the United States exclusively in a single laboratory facility in Memphis, Tennessee, and in the United Kingdom exclusively in a single laboratory facility in Abingdon, England. If these or any future facilities were to be damaged, destroyed or otherwise unable to operate, whether due to fire, floods, hurricanes, storms, tornadoes, other natural disasters, employee malfeasance, terrorist acts, power outages, or otherwise, or if performance of our laboratories is disrupted for any other reason, we may not be able to perform our tests or generate test reports as promptly as our customers expect, or possibly not at all. Building or finding a replacement facility could be difficult, expensive and time consuming and any new laboratory would need to satisfy the various certification, accreditation and licensing requirements to which our current laboratory facilities are subject, including, for example, CLIA requirements in the United States. If we are unable to perform our tests or generate test reports within a timeframe that meets our customers' expectations, our business, financial results and reputation could be materially harmed.

As of December 31, 2014, we maintain insurance coverage totaling \$8.3 million against damage to our property and equipment and an additional \$26.5 million to cover business interruption and research and development restoration expenses, subject to deductibles and other limitations. If we have underestimated our insurance needs with respect to an interruption, however, or if an interruption is not subject to coverage under our insurance policies, we may not be able to cover our losses. Even if we cover our losses, our business, financial results and reputation could be materially harmed.

We may require substantial additional capital resources to fund our operations. We may not be able to obtain additional capital resources on favorable terms and if we cannot find additional capital resources, we may have difficulty operating our business. Raising additional capital may also cause dilution to our existing shareholders.

As of December 31, 2014, we had cash and cash equivalents of \$50.2 million and working capital of \$54.8 million. In addition, we received net proceeds of approximately \$53.7 million through a secondary offering of our ordinary shares that closed on February 4, 2015. We believe we have sufficient resources to fund our projected operations for at least the next few years. However, changing circumstances may cause us to consume capital significantly faster or slower than we currently anticipate. We have based these estimates on assumptions that may prove to be wrong, and we could exhaust our available financial resources sooner than we currently anticipate. In order to fund our strategic plans, we may need to enter into a strategic collaboration or raise additional capital. We may seek to raise additional capital through the issuance of equity or debt securities in the public or private markets, or through a collaborative arrangement or sale of assets. Additional financing opportunities may not be available to us, or if available, may not be on favorable terms. Further, to the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our shareholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of our shareholders. Our future capital requirements will depend on many factors, including revenue generated from the sale of our T-SPOT.TB test, margins, operating expenses and our ability to control costs associated with our operations, and the costs of filing, prosecuting, maintaining, defending and enforcing any patent claims and other intellectual property rights. The availability of additional capital will also depend on many factors, including the market price of our ordinary shares and the availability and cost of additional equity capital from existing and potential new investors, our ability to retain the listing of our ordinary shares on The NASDAQ Global Market and general economic and industry conditions affecting the availability and cost of capital.

Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration, strategic alliance and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates beyond the rights we have already relinquished, or grant licenses on terms that are not favorable to us.

Failure in our information technology or storage systems could significantly disrupt our operations and our research and development efforts, which could adversely impact our revenue, as well as our research, development and commercialization efforts.

Our ability to execute our business strategy depends, in part, on the continued and uninterrupted performance of our information technology, or IT, systems, which support our operations, including our LIS, our billing system, and our customer interfaces. Due to the sophisticated nature of the technology we use in our laboratories and our complex billing procedures, we are substantially dependent on our IT systems. IT systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious human acts and natural disasters. Moreover, despite network security and back-up measures, some of our servers are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our IT systems, sustained or repeated system failures that interrupt our ability to generate and maintain data, and in particular to operate our LIS and billing system, could adversely affect our ability to operate our business. Any interruption in the operation of our LIS or billing system, due to IT system failures, part failures or potential disruptions in the event we are required to relocate our IT systems within our facility or to another facility could have an adverse effect on our operations.

We rely on courier delivery services to transport samples to our facilities for testing. If these delivery services are disrupted, our business and customer satisfaction could be negatively impacted.

Customers in the United States and the United Kingdom ship samples to us by air and ground express courier delivery service for testing in our Memphis, Tennessee and Abingdon, England facilities. If we suffer from disruptions in delivery service, whether due to bad weather, natural disaster, terrorist acts or threats, or for other reasons, we may be unable to provide timely services to customers or at all. As a result, such disruptions could materially and adversely affect our financial results and our reputation.

Because our business relies heavily on international operations and revenue, changes in currency exchange rates and our need to convert currencies may negatively affect our financial condition and results of operations.

Our business relies heavily on our operations outside the United States. For the year ended December 31, 2014, 54% of our total revenue was derived from sales outside the United States. Because we currently operate in three major regions of the world (the United States, Europe and rest of world, or Europe & ROW, and Asia), our revenue is denominated in multiple currencies. Sales in the United States are denominated in U.S. Dollars. Sales in China are denominated in U.S. Dollars and sales in Japan are denominated in Yen but, in each case, these sales are made by our U.K.-based legal entity where the Pound Sterling is the functional currency. As a result, these sales are subject to remeasurement into Pounds Sterling and then translation into U.S. Dollars when we consolidate our financial statements. Sales in Europe are denominated primarily in the Pound Sterling and Euro. As we grow Europe & ROW sales outside the United Kingdom and the European Union countries whose national currency is the Euro, or the Euro Zone, we will be subject to exchange rate risk from additional currencies. As a result, our exchange rate exposure may change over time as our business practices evolve and could result in increased costs or reduced revenue and could affect our actual cash flow. Changes in the relative values of currencies occur regularly and, in some instances, may have a significant impact on our operating results. We cannot predict with any certainty changes in currency exchange rates or the degree to which we can effectively mitigate these risks.

Our future success depends on our ability to successfully develop, obtain clearance or approval for and commercialize new products.

Our future success partially depends on our ability to successfully develop and market new products. Our ability to develop any of these products is dependent on a number of factors, including funding availability to complete development efforts, our ability to develop products that adequately detect or measure the targeted function, condition or disease, our ability to secure required FDA or other regulatory clearance or approval and our ability to obtain licenses to necessary third-party intellectual property. We may encounter problems in the development phase for our products, which can result in substantial setbacks and delays or abandonment of further work on the potential product. There can be no assurance that we will not encounter such setbacks with the products in our pipeline, or that funding from outside sources and our revenue will be sufficient to bring any future product to the point of commercialization.

Even if we are successful in developing new products and securing regulatory approval to market them, we may not be able to achieve marketplace acceptance for our new products or generate significant revenue from their sale. As with our current T-SPOT.TB test, the success of any future products will depend upon the degree of market acceptance by physicians, hospitals, third-party payors and others in the medical community. Achieving market acceptance will require us to expend substantial time and resources to educate physicians and other members of the medical community on the benefits of any new product we develop and we may never be successful in gaining market acceptance of our new products. There can be no assurance that the products we seek to develop will work effectively in the marketplace, or that we will be able to produce them on an economical basis.

We may seek to grow our business through acquisitions of or investments in new or complementary businesses, products or technologies, and the failure to manage acquisitions or investments, or the failure to integrate them with our existing business, could have a material adverse effect on our operating results and the value of our ordinary shares.

From time to time we expect to consider opportunities to acquire or make investments in other technologies, products and businesses that may enhance our capabilities, complement our current products or expand the breadth of our product offerings, markets or customer base. Potential and completed acquisitions and strategic investments involve numerous risks, including:

- difficulties in acquiring new products, technologies or businesses that will help our current business;
- difficulties in integrating acquired personnel, technologies, products or business operations;
- issues maintaining uniform standards, procedures, controls and policies;
- unanticipated costs associated with acquisitions;
- diversion of management's attention from our core business;
- adverse effects on existing business relationships with suppliers and customers;
- risks associated with entering new markets in which we have limited or no experience;
- potential loss of key employees of acquired businesses; and
- increased legal and accounting compliance costs.

On July 31, 2014, we acquired substantially all of the assets of Boulder Diagnostics, Inc. a privately owned company developing immunology-based assays for autoimmune and inflammatory conditions/diseases. This acquisition brought us three additional product pipeline opportunities which we believe are well-suited to the Company's growing commercial infrastructure, but there can be no assurance that we will be able to successfully develop and complete the development or commercialization of the products that we acquired in the acquisition. Further, even if we are able to profitably commercialize the underlying product candidates, there is no guarantee that we will be able to do so before any competitors develop and commercialize similar products.

Any acquisitions we undertake in the future could be expensive and time consuming, and may disrupt our ongoing business and prevent management from focusing on our operations. If we are unable to manage acquisitions or investments, or integrate any acquired businesses, products or technologies effectively, our business, results of operations and financial condition may be materially adversely affected.

If we fail to successfully develop and complete our IPR&D program, our future operating results could be materially adversely impacted.

There can be no assurance that we will be able to successfully develop and complete the acquired IPR&D program and profitably commercialize the underlying product candidates before our competitors develop and commercialize similar products, or at all. Moreover, if the acquired IPR&D program fails or is abandoned during development, then we may not realize the value we have estimated and recorded in our financial statements on the acquisition date, and we may also not recover the research and development investment made since the acquisition date to further develop that program. If such circumstances were to occur, our future operating results could be materially adversely impacted.

Write-offs related to the impairments of our long-lived assets, including goodwill and indefinite-lived intangible assets may adversely impact our results of operations.

We may incur significant non-cash charges related to impairments of our long-lived assets, including goodwill and indefinite-lived intangible assets. Although we did not record any such charges during 2014, we are required to perform periodic impairment reviews of those assets at least annually. To the extent future reviews conclude that the expected future cash flows generated from our business activities are not sufficient to recover the carrying value of these assets, we will be required to measure and record an impairment charge to write-down these assets to their realizable values and those impairment charges could be equal to the entire carrying value.

We completed our last review during the fourth quarter of 2014 and determined that goodwill and indefinite-lived intangible assets were not impaired. However, there can be no assurance that upon completion of subsequent reviews a material impairment charge will not be recorded. If future periodic reviews determine that our assets are impaired and a write-down is required, it could adversely impact our operating results.

Our business could suffer if we lose the services of, or are unable to attract and retain, key members of our senior management, key advisors or other personnel.

We are dependent upon the continued services of key members of our senior management and a limited number of key advisors and personnel. In particular, we are highly dependent on the skills and leadership of our Chief Executive Officer, Dr. Peter Wrighton-Smith, and the other members of management named in the “Management” section elsewhere in this Annual Report. The loss of any one of these individuals could disrupt our operations or our strategic plans. Additionally, our future success will depend on, among other things, our ability to continue to hire and retain the necessary qualified scientific, technical, sales, marketing and managerial personnel, for whom we compete with numerous other companies, academic institutions and organizations. The loss of members of our management team, key advisors or personnel, or our inability to attract or retain other qualified personnel or advisors, could have a material adverse effect on our business, results of operations and financial condition. Although all members of our senior management team have entered into agreements that restrict their ability to compete with us for a period of time after the end of their employment, we may be unable to enforce such restrictive covenants at all or for a sufficient duration of time to prevent members of our management team from competing with us.

Our ability to use net operating losses to offset future taxable income may be subject to substantial limitations.

As of December 31, 2014, our available U.S. federal net operating losses, or NOLs, totaled \$71.9 million and U.S. state loss carryforwards totaled \$63.6 million. The amount of these NOLs remains subject to review and possible adjustment by the Internal Revenue Service and state revenue authorities, as applicable. NOLs may become subject to an annual limitation if there is a cumulative change in the ownership interest of significant shareholders (or certain shareholder groups) over a three-year period in excess of 50%, in accordance with rules established under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, and similar state rules (we refer to each as an ownership change). Such an ownership change could limit the amount of historic NOLs that can be utilized annually to offset future taxable income. The amount of this annual limitation is determined based on the value of the Company immediately prior to the ownership change. We have completed several financings since our inception, as well as the initial public offering, or IPO, of our ordinary shares, that may have resulted in one or more ownership changes under this definition. If we are deemed to have undergone an ownership change by virtue of these transactions, we may not be able to utilize a material portion of our NOLs even if we attain profitability. Future changes in our share ownership, some of which are outside of our control, could result in additional ownership changes for purposes of these rules. We are unable to predict future ownership changes or the way an ownership change could limit the use of our NOLs.

Risks related to regulatory and other legal issues.

If we fail to comply with extensive regulations of domestic and international regulatory authorities, sales of our T-SPOT.TB test in new markets and the development and commercialization of any new product candidates could be delayed or prevented.

Our T-SPOT.TB test is, and any new product candidates will be, subject to extensive government regulations related to development, testing, manufacturing and commercialization in the United States and other countries before we can sell in these markets. The process of obtaining and complying with FDA and other governmental regulatory approvals and regulations is costly, time consuming, uncertain and subject to unanticipated delays. Securing regulatory approval for a new product, in the United States and many other countries, typically requires several years. Despite the time and expense exerted, regulatory approval is never guaranteed. We may not be able to obtain FDA or other required regulatory approval and market any further products we may develop during the time we anticipate, or at all. We also are subject to the following risks and obligations, among others:

- regulators may refuse to approve an application if they believe that applicable regulatory criteria are not satisfied;
- regulators may require additional testing for safety and effectiveness;
- regulators may interpret data from clinical studies in different ways than we interpret them;
- if regulatory approval of a product is granted, the approval may be limited to specific indications or limited with respect to its distribution; and
- regulators may change their approval policies and/or adopt new regulations that affect our ability to secure approvals for new products, which would decrease the chance we would be able to commercialize new diagnostic tests.

[Table Of Contents](#)

In addition, some international jurisdictions, such as China, require periodic recertification. Even if we obtain initial certifications from regulatory bodies, we may lose certification after a periodic review. Failure to maintain requisite certifications from regulatory bodies would adversely affect our ability to generate future revenue and operating income.

If we or our suppliers fail to comply with ongoing regulatory requirements, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.

Any product for which we obtain marketing approval in the United States or in international jurisdictions, along with the manufacturing processes, post-approval clinical data and promotional activities for such product, will be subject to continual review and periodic inspections by the FDA and other regulatory bodies. Furthermore, our suppliers may be subject to similar regulatory oversight, and may not currently be or may not continue to be in compliance with applicable regulatory requirements. Failure by us or one of our suppliers to comply with statutes and regulations administered by the FDA and other regulatory bodies, or failure to take adequate action in response to any observations, could result in, among other things, any of the following enforcement actions:

- warning letters or untitled letters;
- fines and civil penalties;
- unanticipated expenditures for corrective actions;
- delays in approving, or refusal to approve, our products;
- withdrawal or suspension of approval by the FDA or other regulatory bodies;
- product recall or seizures;
- interruption of production;
- operating restrictions;
- injunctions; and
- criminal penalties.

If any of these actions were to occur, it could harm our reputation and could cause our product sales and profitability to suffer.

Any regulatory approval of a product may also be subject to limitations on the indicated uses for which the product may be marketed. If the FDA or another regulatory body determines that our promotional materials, training or other activities constitute promotion of an unapproved use, it could request that we cease or modify our training or promotional materials or subject us to regulatory enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our training or promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under applicable statutory authorities, such as laws prohibiting false claims for reimbursement.

Additionally, we may be required to conduct costly post-market testing, and we will be required to report adverse events and malfunctions related to our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements may result in restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties.

Furthermore, the FDA and various other authorities will inspect our facilities and those of our suppliers from time to time to determine whether we are in compliance with regulations relating to the manufacture of diagnostic products, including regulations concerning design, manufacture, testing, quality control, product labeling, distribution, promotion and record-keeping practices. A determination that we are in material violation of such regulations could lead to the imposition of civil penalties, including fines, product recalls, product seizures or, in extreme cases, criminal sanctions.

If we are unable to comply with the requirements of CLIA and state laws governing clinical laboratories or if we are required to expend significant additional resources to comply with these requirements, the success of our business could be threatened.

HHS has classified our T-SPOT.TB test as a high-complexity test under CLIA. Under CLIA, personnel requirements for laboratories conducting high-complexity tests are more stringent than those applicable to laboratories performing less complex tests. As a result of these personnel requirements, we must employ more experienced or more highly educated personnel and additional categories of employees, which increases our operating costs. If we fail to meet CLIA requirements, HHS or state agencies could require us to cease our T-SPOT.TB testing or other testing subject to CLIA that we may develop in the future. Continued compliance with CLIA requirements may cause us to incur significant expenses and potentially lose revenue in doing so. Moreover, new interpretations of current regulations or future changes in regulations under CLIA may make it difficult or impossible for us to comply with our CLIA classification, which would significantly harm our business.

[Table Of Contents](#)

Many states in which our physician and laboratory clients are located, such as New York, have laws and regulations governing clinical laboratories that are more stringent than federal law and may apply to us even if we are not located, and do not perform our T-SPOT.*TB* test, in that state. We may also be subject to additional licensing requirements as we expand our sales and operations into new geographic areas, which could impair our ability to pursue our growth strategy.

We may potentially be subject to product liability claims.

The testing, manufacturing and marketing of medical diagnostic tests such as our T-SPOT.*TB* test entail an inherent risk of product liability claims. Further, providing clinical testing services entails a risk of claims for errors or omissions made by our laboratory staff. Potential liability claims may exceed the amount of our insurance coverage or may be excluded from coverage under the terms of the policy. As of December 31, 2014, we had product liability insurance of \$15.3 million. Our existing insurance will have to be increased in the future if we are successful at introducing new diagnostic products and this will increase our costs. Under certain of our customer and license agreements, we have agreed to provide indemnification for product liability claims arising out of the use of our T-SPOT.*TB* test. In the event that we are held liable for a claim or for damages exceeding the limits of our insurance coverage, we may be required to make substantial payments.

Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our product and product candidates;
- injury to our reputation;
- costs of related litigation;
- substantial monetary awards to patients and others;
- loss of revenue; and
- the inability to commercialize our products and product candidates.

Any of these outcomes may have an adverse effect on our consolidated results of operations, financial condition and cash flows, and may increase the volatility of our share price.

Our inadvertent or unintentional failure to comply with the complex government regulations concerning privacy of medical records could subject us to fines and adversely affect our reputation.

The U.S. federal privacy regulations limit use or disclosure of protected health information, without written patient authorization, to purposes of payment, treatment or healthcare operations (as defined under HIPAA) except for disclosures for various public policy purposes and other permitted purposes outlined in the privacy regulations. The privacy regulations provide for significant fines and other penalties for wrongful use or disclosure of protected health information, including potential civil and criminal fines and penalties.

We have policies and practices that we believe make us compliant with the privacy regulations. Nevertheless, the documentation and process requirements of the privacy regulations are complex and subject to interpretation. Failure to comply with the privacy regulations could subject us to sanctions or penalties, loss of business and negative publicity.

The privacy regulations establish a “floor” of minimum protection for patients as to their medical information and do not supersede state laws that are more stringent. Therefore, we are required to comply with both HIPAA privacy regulations and various state privacy laws. Although the HIPAA statute and regulations do not expressly provide for a private right of action, we could incur damages under state laws to private parties for the wrongful use or disclosure of confidential health information or other private personal information. Internationally, virtually every jurisdiction in which we operate has established its own data security and privacy legal framework with which we or our customers must comply, including the Data Protection Directive established in the European Union. We may also need to comply with varying and possibly conflicting privacy laws and regulations in other jurisdictions. As a result, we could face regulatory actions, including significant fines or penalties, adverse publicity and possible loss of business.

A disruption in our computer networks, including those related to cybersecurity, could adversely affect our financial performance.

We rely on our computer networks and systems, some of which are managed by third parties, to manage and store electronic information (including sensitive data such as confidential business information and personally identifiable data relating to employees, customers and other business partners), and to manage or support a variety of critical business processes and activities. We may face threats to our networks from unauthorized access, security breaches and other system disruptions. Despite our security measures, our infrastructure may be vulnerable to attacks by hackers or other disruptive problems. Any such security breach may compromise information stored on our networks and may result in significant data losses or theft of sensitive or proprietary information. A cybersecurity breach could hurt our reputation by adversely affecting the perception of customers and potential customers of the security of their orders and personal information. In addition, a cybersecurity attack could result in other negative consequences, including disruption of our internal operations, increased cyber security protection costs, lost revenue, regulatory actions or litigation. Any disruption of could also have a material adverse impact on our operations.

Our use of biological and hazardous materials and waste requires us to comply with regulatory requirements, including environmental, health and safety laws, regulations and permit requirements and subjects us to significant costs and exposes us to potential liabilities.

The handling of materials used in the diagnostic testing process involves the controlled use of biological and hazardous materials and wastes. The primary hazardous materials we handle or use include human blood samples and solvents. Our business and facilities and those of our suppliers are subject to federal, state, local and foreign laws and regulations relating to the protection of human health and the environment, including those governing the use, manufacture, storage, handling and disposal of, and exposure to, such materials and wastes. In addition, under some environmental laws and regulations, we could be held responsible for costs relating to any contamination at our past or present facilities and at third-party waste disposal sites even if such contamination was not caused by us. A failure to comply with current or future environmental laws and regulations, including the failure to obtain, maintain or comply with any required permits, could result in severe fines or penalties. Any such expenses or liability could have a significant negative impact on our business, results of operations and financial condition. In addition, we may be required to incur significant costs to comply with regulatory requirements in the future.

Our business arrangements with customers and third-party payors are subject to applicable anti-kickback, anti-fraud and abuse and other healthcare laws and regulations. If such business arrangements fail to comply with these laws and regulations, we could be exposed to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors play a primary role in the recommendation and ordering of any product candidates, including our T-SPOT.TB test, for which we obtain marketing approval. Our arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our product. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- The U.S. federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federally funded healthcare programs such as Medicare and Medicaid. This statute has been broadly interpreted to apply to manufacturer arrangements with prescribers, purchasers and formulary managers, among others. Several other countries, including the United Kingdom, have enacted similar anti-kickback, fraud and abuse, and healthcare laws and regulations.
- The U.S. False Claims Act imposes criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government.
- HIPAA imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. HIPAA also imposes criminal liability for knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services.
- The federal Physician Payment Sunshine Act requirements under the PPACA require manufacturers of drugs, devices, biologics and medical supplies to report to HHS information related to payments and other transfers of value made to or at the request of covered recipients, such as physicians and teaching hospitals, and physician ownership and investment interests in such manufacturers. Payments made to physicians and research institutions for clinical trials are included within the ambit of this law. Certain state laws and regulations also require the reporting of certain items of value provided to health care professionals.
- Analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations involve substantial costs. We may be subject to *qui tam* litigation brought by private individuals on behalf of the government under the U.S. Federal False Claims Act, which would include claims for up to treble damages. Additionally, it is possible that governmental authorities would conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. Exclusion, suspension and debarment from government funded healthcare programs would significantly impact our ability to commercialize, sell or distribute any product. If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

We are subject to the U.K. Bribery Act, the U.S. Foreign Corrupt Practices Act and other anti-corruption laws, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures, and legal expenses, which could adversely affect our business, results of operations and financial condition.

Our operations are subject to anti-corruption laws, including the U.K. Bribery Act 2010, or Bribery Act, the U.S. Foreign Corrupt Practices Act, or FCPA, and other anti-corruption laws that apply in countries where we do business. The Bribery Act, FCPA and these other laws generally prohibit us and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. We and our commercial partners operate in a number of jurisdictions that pose a high risk of potential Bribery Act or FCPA violations, and we participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the Bribery Act, FCPA or local anti-corruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted.

We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the United Kingdom and the United States, and authorities in the European Union, including applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange regulations, collectively referred to as the Trade Control laws.

There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the Bribery Act, the FCPA or other legal requirements, including Trade Control laws. If we violate provisions of the Bribery Act, the FCPA or other anti-corruption laws or Trade Control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. Likewise, any investigation into or audit of the Company of any potential violations of the Bribery Act, the FCPA, other anti-corruption laws or Trade Control laws by U.K., U.S. or other authorities could subject us to fines or criminal or other penalties, which could have an adverse impact on our reputation, our business, results of operations and financial condition.

Healthcare reform measures could hinder or prevent the commercial success of our diagnostic tests.

In March 2010, President Obama signed into law a legislative overhaul of the U.S. healthcare system, the PPACA, which may have far-reaching consequences for many healthcare companies, including diagnostic companies like us. For example, if reimbursement for our diagnostic tests is substantially less than we or our clinical laboratory customers expect, our business could be materially and adversely impacted.

Regardless of the impact of the PPACA on us, the U.S. government and other governments have shown significant interest in pursuing healthcare reform and reducing healthcare costs. Any government-adopted reform measures could cause significant pressure on the pricing of healthcare products and services, including our T-SPOT.TB test, in the United States and internationally, as well as the amount of reimbursement available from governmental agencies and other third-party payors.

Risks related to our intellectual property.

We may be unable to protect or obtain proprietary rights that we utilize or intend to utilize.

In developing, manufacturing and using our T-SPOT.TB test, we employ a variety of proprietary and patented technologies, including technologies we license from third parties. We have licensed, and expect to continue to license, various other technologies and methods. We cannot provide any assurance that the intellectual property rights that we own or license provide protection from competitive threats or that we would prevail in any challenge mounted to our intellectual property rights. In addition, we cannot provide any assurances that we will be successful in obtaining and retaining licenses or proprietary or patented technologies in the future.

We are unable to predict whether any of our currently pending or future patent applications will result in issued patents, or how long it may take for such patents to be issued. Further, we cannot predict whether other parties will challenge any patents issued or licensed to us or that courts or administrative agencies will hold our patents or the patents we license to be valid and enforceable. We may not be successful in defending challenges made against our patents and patent applications. Any successful third-party challenge to our patents could result in the unenforceability or invalidity of such patents. Both the patent application process and the process of managing patent disputes can be time consuming and expensive.

[Table Of Contents](#)

The patent positions of life sciences companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in such companies' patents has emerged to date in the United States. Furthermore, in the biotechnology field, courts frequently render opinions that may affect the patentability of certain inventions or discoveries and the patent positions of companies engaged in development and commercialization of certain diagnostic tests. Various courts, including the U.S. Supreme Court, have recently rendered decisions that impact the scope of patentability of certain inventions or discoveries relating to genomic diagnostics. These decisions generally stand for the proposition that inventions that recite laws of nature are not themselves patentable unless they have sufficient additional features that provide practical assurance that the processes are genuine inventive applications of those laws rather than patent drafting efforts designed to monopolize the law of nature itself. What constitutes a "sufficient" additional feature is uncertain. While we do not generally rely on gene sequence patents, this evolving case law in the United States may adversely impact our ability to obtain new patents and may facilitate third-party challenges to our existing owned and licensed patents.

Changes in either the patent laws or in interpretations of patent laws in the United States or other countries may diminish the value of our intellectual property rights. We cannot predict the breadth of claims that may be allowed or enforced in patents we own or in those to which we have license rights. For example:

- the inventor might not have been the first to make the inventions covered by patents we rely on;
- the inventor or his assignee might not have been the first to file patent applications for the claimed inventions;
- others may independently develop similar or alternative products and technologies or duplicate our product and technologies;
- it is possible that the patents we own or license may not provide us with any competitive advantages, or may be challenged and invalidated by third parties;
- any patents we obtain or license may expire before, or shortly after, the products and services relating to such patents are commercialized;
- we may not develop additional proprietary products and technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

In particular, in September 2011, the U.S. Congress passed the Leahy-Smith America Invents Act, or the AIA, which became effective in March 2013. The AIA reforms U.S. patent law in part by changing the standard for patent approval for certain patents from a "first to invent" standard to a "first to file" standard and developing a post-grant review system. It is too early to determine what the effect or impact the AIA will have on the operation of our business and the protection and enforcement of our intellectual property. However, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

Some patent applications in the United States may be maintained in secrecy until the patents are issued, other patent applications in the United States and many foreign jurisdictions are not published until eighteen months after filing, and publications in the scientific literature often lag behind actual discoveries. We therefore cannot be certain that others have not filed patent applications for technology covered by issued patents or pending applications that we own or license or that we or our licensors, as applicable, were the first to invent the technology (pre-AIA) or first to file (post-AIA). Our competitors may have filed, and may in the future file, patent applications covering technology similar or the same as ours. Any such patent application may have priority over patent applications that we own or license and could further require us to obtain rights to such technologies in order to carry on our business. If another party has filed a U.S. patent application on inventions similar or the same as those that we own or license, we or our licensors may have to participate in an interference or other proceeding in the U.S. Patent and Trademark Office, or PTO, or a court to determine priority of invention in the United States, for pre-AIA applications and patents. For post-AIA applications and patents, we or our licensors may have to participate in a derivation proceeding to resolve disputes relating to inventorship. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss of our U.S. patent position with respect to such inventions.

Some of our competitors may be able to sustain the costs of complex patent disputes and litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any disputes or litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

In addition to pursuing patents on our technology, we seek to protect our intellectual property and proprietary technology by entering into intellectual property assignment agreements with our employees, consultants and third party collaborators. See "—We may be unable to adequately prevent disclosure of trade secrets and other proprietary information."

Our intellectual property rights may not be sufficient to protect our competitive position and to prevent others from manufacturing, using or selling competing products.

The scope of our owned and licensed intellectual property rights may not be sufficient to prevent others from manufacturing, using or selling competing tests. For example, our intellectual property position depends in part on intellectual property that we license from third parties. However, many of the key patents we license are expected to expire by 2020. In addition, while many of the licenses we have been granted are exclusive, such rights may be limited to a narrowly defined field of use. As a result, our competitors may have obtained or be able to obtain a license to the same intellectual property in a closely related field of use. Finally, we have also granted sublicenses to third parties under certain of the intellectual property that we license. Such sublicenses may allow third parties or their licensees to market a TB test that would otherwise infringe upon such intellectual property.

[Table Of Contents](#)

Moreover, competitors could purchase our product and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. If our intellectual property is not adequately protected so as to protect our market against competitors' products and methods, our competitive position could be adversely affected, as could our business.

We depend on certain technologies that are licensed or sublicensed to us. We do not control these technologies and any loss of our rights to them could prevent us from selling our product.

We rely on licenses in order to be able to use various proprietary technologies that are material to our business. For example, we licensed technology relating to the use of the ELISPOT technique, which forms part of the core platform of our T.SPOT technology, from Isis Innovation Limited, and we license the use of other patents to protect our T.SPOT.TB product from the Statens Serum Institut and Rutgers. While the patents that we licensed from Isis have been assigned to us, we still have certain obligations to Isis, including an obligation to pay royalties. See "Business—Intellectual property—Our license and assignment agreements." Otherwise, we do not own the patents that underlie these licenses. Our rights to use these technologies and employ the inventions claimed in the licensed patents are subject to the continuation of and our compliance with the terms of those licenses.

In some cases, we do not control the prosecution, maintenance or filing of the patents to which we hold licenses. Enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents is often subject to the control or cooperation of our licensors. We cannot be certain that our licensors will prosecute, maintain, enforce and defend the licensed patent rights in a manner consistent with the best interests of our business. We also cannot be certain that drafting or prosecution of the licensed patents and patent applications by the licensors have been or will be conducted in compliance with applicable laws and regulations, will result in valid and enforceable patents and other intellectual property rights, or that any issued patents or patents that may issue in the future will provide any competitive advantage.

Certain of our licenses contain provisions that allow the licensor to terminate the license upon specific conditions. Our rights under each of the licenses are subject to our continued compliance with the terms of the license, including certain diligence, disclosure and confidentiality obligations and the payment of royalties and other fees. If we were found to be in breach of any of our license agreements, in certain circumstances our licensors may take action against us, including termination of the applicable license. Because of the complexity of our product and the patents we have licensed, determining the scope of the license and related obligations can be difficult and can lead to disputes between us and the licensor. An unfavorable resolution of such a dispute could lead to an increase in the royalties payable pursuant to the license or termination of the license. If a licensor believed we were not paying the royalties due under the license or were otherwise not in compliance with the terms of the license, the licensor may have the right to terminate the license or, in certain circumstances, to convert an exclusive license to a non-exclusive one. If such an event were to occur, the value of our product or product candidates could be materially adversely affected, we might be barred from producing and selling some or all of our products and may be subject to other liabilities.

In addition to the above risks, certain of our licensors do not own certain intellectual property included in the license, but instead have licensed such intellectual property from a third party, and have granted us a sub-license. As a result, the actions of our licensors or of the ultimate owners of the intellectual property may affect our rights to use our sublicensed intellectual property, even if we are in compliance with all of the obligations under our license agreements. For example, one of our licenses comprises a sublicense to us of certain patent rights owned by a third party that is not our direct licensor. If our licensors were to fail to comply with their obligations under the agreements pursuant to which they obtain the rights that are sublicensed to us, or should such agreements be terminated or amended, our ability to produce and sell our product and product candidates may be materially harmed. Finally, the legal issues surrounding the treatment of intellectual property licenses in bankruptcy proceedings are complex and may vary from jurisdiction to jurisdiction. We therefore cannot provide assurance that we would not lose some or all of our rights under a license if the applicable licensor was involved in such proceedings.

We may become involved in disputes relating to our intellectual property rights, and may need to resort to litigation in order to defend and enforce our intellectual property rights. In addition, we could face claims that our activities or the manufacture, use or sale of our products infringe the intellectual property rights of others, which could cause us to pay substantial damages or licensing fees and limit our ability to sell some or all of our products and services.

Extensive litigation regarding patents and other intellectual property rights has been common in the medical diagnostics industry. Litigation may be necessary to assert infringement claims, enforce patent rights, protect trade secrets or know-how and determine the enforceability, scope and validity of certain proprietary rights. Litigation may even be necessary to resolve disputes of inventorship or ownership of proprietary rights. The defense and prosecution of intellectual property lawsuits, PTO interference or derivation proceedings, and related legal and administrative proceedings (e.g., a reexamination) in the U.S. and internationally involve complex legal and factual questions. As a result, such proceedings are costly and time consuming to pursue, and their outcome is uncertain.

[Table Of Contents](#)

Even if we prevail in such a proceeding, the remedy we obtain may not be commercially meaningful or adequately compensate us for any damages we may have suffered. If we do not prevail in such a proceeding, our patents could potentially be declared to be invalid, unenforceable or narrowed in scope, or we could otherwise lose valuable intellectual property rights. Similar proceedings involving the intellectual property we license could also have an impact on our business. For example, the scope of one of the European patents that we license from Rutgers, The State University of New Jersey, was recently narrowed as a result of a third party opposition proceeding before the European Patent Office. The decision is currently under appeal and the outcome of that appeal may adversely affect our competitive position. Further, if any of our other owned or licensed patents are declared invalid, unenforceable or narrowed in scope, our competitive position could be adversely affected.

In addition, our research, development and commercialization activities, including our T-SPOT.TB test, may infringe or be claimed to infringe patents or other intellectual property rights owned by other parties. Certain of our competitors and other companies have substantial patent portfolios, and may attempt to use patent litigation as a means to obtain a competitive advantage or to extract licensing revenue. The risks of being involved in such litigation may also increase as we gain greater visibility as a public company and as we gain commercial acceptance of our products and move into new markets and applications for our products. For example, we are aware of an issued U.S. patent owned by a third party which claims technology that may be relevant to our T-SPOT.TB test. We believe this patent is invalid and/or unenforceable, and we therefore challenged the validity of the patent through an ex parte reexamination proceeding before the PTO. Although the validity of the patent was upheld in that proceeding, we continue to believe that the patent is invalid and/or unenforceable based in part on information we discovered after the PTO's decision in the reexamination proceeding. Nevertheless, if the patent holder were to pursue an infringement claim against us and we were unable to either negotiate acceptable license terms or otherwise resolve the matter, we could incur substantial expense to defend a claim, we could be ordered to pay substantial damages for infringement, and we could be enjoined from future conduct that would infringe the patent, which may include the making, using and selling of our T-SPOT.TB test in the United States. There may also be patents and patent applications that are relevant to our technologies or tests that we are not aware of. For example, certain relevant patent applications may have been filed but not published. If such patents exist, or if a patent issues on any of such patent applications, that patent could be asserted against us. In addition to patent infringement claims, we may also be subject to other claims relating to the violation of intellectual property rights, such as claims that we have misappropriated trade secrets or infringed third party trademarks.

Regardless of merit or outcome, our involvement in any litigation, interference or other administrative proceedings could cause us to incur substantial expense and could significantly divert the efforts of our technical and management personnel. Any public announcements related to litigation or interference proceedings initiated or threatened against us could cause our share price to decline. An adverse determination, or any actions we take or agreements we enter into in order to resolve or avoid disputes, may subject us to the loss of our proprietary position or to significant liabilities, or require us to seek licenses that may include substantial cost and ongoing royalties. Licenses may not be available from third parties, or may not be obtainable on satisfactory terms. An adverse determination or a failure to obtain necessary licenses may restrict or prevent us from manufacturing and selling our products and offering our services. These outcomes could materially harm our business, financial condition and results of operations.

We may not be able to adequately protect our intellectual property outside of the United States.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology, which could make it difficult for us to stop the infringement of our licensed and owned patents. For example, we are aware that third parties, particularly in China, are currently selling TB diagnostic products that we believe are covered by certain patents we license. We do not know whether our licensor will take all necessary steps to enforce its patent rights in China or whether it will obtain effective relief to stop the sale of products that infringe on its patent rights. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. Additionally, prosecuting and maintaining intellectual property (particularly patent) rights are very costly endeavors, and for these and other reasons we may not pursue or obtain patent protection in all major markets. We do not know whether legal and government fees will increase substantially and therefore are unable to predict whether cost may factor into our global intellectual property strategy.

In addition to the risks associated with patent rights, the laws in some foreign jurisdictions may not provide protection for our trade secrets and other intellectual property. If our trade secrets or other intellectual property are misappropriated in foreign jurisdictions, we may be without adequate remedies to address these issues. Additionally, we also rely on confidentiality and assignment of invention agreements to protect our intellectual property in foreign jurisdictions. These agreements may provide for contractual remedies in the event of misappropriation, but we do not know to what extent, if any, these agreements and any remedies for their breach, will be enforced by a foreign court. In the event our intellectual property is misappropriated or infringed upon and an adequate remedy is not available, our future prospects will likely diminish. The sale of products that infringe our intellectual property rights, particularly if such products are offered at a lower cost, could negatively impact our ability to achieve commercial success and may materially and adversely harm our business.

Our failure to secure trademark registrations could adversely affect our business and our ability to market our product and product candidates.

Our trademark applications in the United States and any other jurisdictions where we may file may not be allowed for registration, and our registered trademarks may not be maintained or enforced. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the PTO and in corresponding foreign agencies, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our applications and/or registrations, and our applications and/or registrations may not survive such proceedings. Failure to secure such trademark registrations in the United States and in foreign jurisdictions could adversely affect our business and our ability to market our product and product candidates.

Obtaining and maintaining our patent protection depends upon compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The PTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent prosecution process and following the issuance of a patent. There are situations in which noncompliance with these requirements can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case if our patent were in force.

We may be unable to adequately prevent disclosure of trade secrets and other proprietary information, or the misappropriation of the intellectual property we regard as our own.

We rely on trade secrets to protect our proprietary know-how and technological advances, particularly where we do not believe patent protection is appropriate or obtainable. Nevertheless, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, third party collaborators and other advisors to protect our trade secrets and other proprietary information. These agreements generally require that the other party to the agreement keep confidential and not disclose to third parties all confidential information developed by the party or made known to the party by us during the course of the party's relationship with us. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Monitoring unauthorized disclosure is difficult, and we do not know whether the steps we have taken to prevent such disclosure are, or will be, adequate. If we were to seek to pursue a claim that a third party had illegally obtained and was using our trade secrets, it would be expensive and time consuming, and the outcome would be unpredictable. Further, courts outside the United States may be less willing to protect trade secrets. In addition, others may independently discover our trade secrets and proprietary information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights. In addition, our trade secrets and proprietary information may be misappropriated as a result of breaches of our electronic or physical security systems in which case we may have no legal recourse. Failure to obtain, or maintain, trade secret protection could enable competitors to use our proprietary information to develop products that compete with our product or cause additional, material adverse effects upon our competitive business position.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the medical diagnostics industry, we employ individuals who were previously employed at other medical diagnostics companies, including our competitors or potential competitors. We may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Risks related to our ordinary shares.

We are eligible to be treated as an emerging growth company and we cannot be certain that the reduced disclosure requirements applicable to emerging growth companies will not make our ordinary shares less attractive to investors.

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act, or JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including (1) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, (2) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (3) exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our ordinary shares less attractive because we may rely on these exemptions. If some investors find our ordinary shares less attractive as a result, there may be a less active trading market for our ordinary shares and our share price may be more volatile.

[Table Of Contents](#)

We could be an emerging growth company for up to five years following our IPO, although certain circumstances could cause us to lose that status earlier, including if the market value of our ordinary shares held by non-affiliates exceeds \$700.0 million as of any June 30 in any fiscal year before that time or if we have total annual gross revenue of \$1.0 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following December 31 or, if we issue more than \$1.0 billion in non-convertible debt during any three-year period before that time, we would cease to be an emerging growth company immediately.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Our share price may be volatile.

Like other early-stage medical diagnostic companies, the market price of our ordinary shares may be volatile. The factors below may also have a material adverse effect on the market price of our ordinary shares:

- fluctuations in our results of operations;
- our ability to enter new markets;
- negative publicity;
- changes in securities or industry analyst recommendations regarding our company, the sectors in which we operate, the securities market generally and conditions in the financial markets;
- regulatory developments affecting our industry;
- announcements of studies and reports relating to our products or those of our competitors;
- changes in economic performance or market valuations of our competitors;
- actual or anticipated fluctuations in our quarterly results;
- conditions in the industries in which we operate;
- announcements by us or our competitors of new products, acquisitions, strategic relations, joint ventures or capital commitments;
- additions to or departures of our key executives and employees;
- fluctuations of exchange rates;
- release or expiry of lock-up or other transfer restrictions on our outstanding ordinary shares; and
- sales or perceived sales of additional shares of our ordinary shares.

In addition, the equity markets have recently experienced significant volatility, particularly with respect to the securities of life sciences companies. The volatility of the securities of life sciences companies often does not relate to the operating performance of those companies. As we operate in a single industry, we are especially vulnerable to these factors to the extent that they affect our industry or our products, or to a lesser extent our markets. In the past, securities class action litigation has often been initiated against companies following periods of volatility in their stock price. This type of litigation could result in substantial costs and divert our management's attention and resources, and could also require us to make substantial payments to satisfy judgments or to settle litigation.

We do not intend to pay cash dividends on our ordinary shares in the foreseeable future.

We have never paid dividends on ordinary shares and do not anticipate paying any cash dividends on our ordinary shares in the foreseeable future. Under English law, any payment of dividends would be subject to relevant legislation and our articles of association, which provide that all dividends must be approved by our Board of Directors and, in some cases, our shareholders, and may only be paid from our distributable profits available for the purpose, determined on an unconsolidated basis.

Our institutional investors and management own a significant percentage of our ordinary shares and will be able to exercise significant influence over matters subject to shareholder approval.

Our executive officers, directors and several investment funds, together with their respective affiliates, beneficially own a substantial percentage of our shares. We expect that these shareholders will be able to exert a significant degree of influence over our management and affairs and over matters requiring shareholder approval, including the election of our Board of Directors and approval of significant corporate transactions. This concentration of ownership could have the effect of entrenching our management and/or our Board of Directors, delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material and adverse effect on the fair market value of our ordinary shares.

We incur increased costs as a result of being a public company whose ordinary shares are publicly traded in the United States and our management must devote substantial time to public company compliance programs.

As a public company, we have incurred and will continue to incur significant legal, insurance, accounting and other expenses that we did not incur as a private company. We intend to continue to invest resources to comply with evolving laws, regulations and standards, and this investment will result in increased general and administrative expenses and may divert management's time and attention. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed. Our insurance costs have increased, particularly for directors and officers liability insurance. Such costs may further increase in the future, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our Board of Directors, particularly to serve on our audit committee and remuneration committee, and qualified executive officers.

Pursuant to Section 404 of the Sarbanes-Oxley Act, or Section 404, we are required to furnish a report by our management on our internal control over financial reporting, and, once we cease to be an emerging growth company, will be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal controls in the future.

Our ordinary shares are listed on The NASDAQ Global Market, but we cannot guarantee that we will be able to satisfy the continued listing standards going forward.

Although our ordinary shares are listed on The NASDAQ Global Market, we cannot ensure that we will be able to satisfy the continued listing standards of The NASDAQ Global Market going forward. If we cannot satisfy the continued listing standards going forward, The NASDAQ Stock Market may commence delisting procedures against us, which could result in our ordinary shares being removed from listing on The NASDAQ Global Market. If our ordinary shares were to be delisted, the liquidity of our ordinary shares could be adversely affected and the market price of our ordinary shares could decrease. Delisting could also adversely affect our shareholders' ability to trade or obtain quotations on our shares because of lower trading volumes and transaction delays. These factors could contribute to lower prices and larger spreads in the bid and ask price for our ordinary shares. You may also not be able to resell your shares at or above the price you paid for such shares or at all.

English law and provisions in our articles of association may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our shareholders, and may prevent attempts by our shareholders to replace or remove our current management.

Certain provisions of English law and our articles of association may have the effect of delaying or preventing a change in control of us or changes in our management. For example, English law and our articles of association include provisions that:

- create a classified Board of Directors whose members serve staggered three-year terms;
- prohibit shareholder action by written resolution;
- establish an advance notice procedure for shareholder approvals to be brought before an annual meeting of our shareholders, including proposed nominations of persons for election to our Board of Directors; and
- provide that vacancies on our Board of Directors may be filled only by a majority of directors then in office, even though less than a quorum.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management. See also “—Provisions in the U.K. City Code on Takeovers and Mergers may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our shareholders.”

Our holding company structure makes us dependent on the operations of our subsidiaries to meet our financial obligations.

We are a public limited company organized under the laws of England and Wales and have no significant assets other than our interest in Oxford Immunotec Limited and its subsidiaries. As a result, we rely exclusively upon payments, dividends and distributions from our direct and indirect subsidiaries for our cash flows. Our ability to pay dividends to our shareholders is dependent on the ability of our subsidiaries to generate sufficient net income and cash flows to pay upstream dividends and make loans or loan repayments.

Risks related to being an English company listing ordinary shares.

U.S. investors may have difficulty enforcing civil liabilities against our company, our directors or members of senior management.

We are incorporated under the laws of England and Wales. The rights of holders of our ordinary shares are governed by English law, including the provisions of the Companies Act 2006, and by our articles of association. These rights differ in certain respects from the rights of shareholders in typical U.S. corporations organized in Delaware. Many of our directors and officers reside outside the United States, and a substantial portion of our assets and all or a substantial portion of the assets of such persons are located outside the United States. As a result, it may be difficult for you to serve legal process on us or our directors and executive officers or have any of them appear in a U.S. court. The United States and the United Kingdom do not currently have a treaty providing for the recognition and enforcement of judgments, other than arbitration awards, in civil and commercial matters. The enforceability of any judgment of a U.S. federal or state court in the United Kingdom will depend on the laws and any treaties in effect at the time, including conflicts of laws principles (such as those bearing on the question of whether a U.K. court would recognize the basis on which a U.S. court had purported to exercise jurisdiction over a defendant). In this context, there is doubt as to the enforceability in the United Kingdom of civil liabilities based solely on the federal securities laws of the United States. In addition, awards for punitive damages in actions brought in the United States or elsewhere may be unenforceable in the United Kingdom. An award for monetary damages under the U.S. securities laws would likely be considered punitive if it did not seek to compensate the claimant for loss or damage suffered and was intended to punish the defendant.

Provisions in the U.K. City Code on Takeovers and Mergers may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our shareholders.

The U.K. City Code on Takeovers and Mergers, or the Takeover Code, applies, among other things, to an offer for a public company whose registered office is in the United Kingdom (or the Channel Islands or the Isle of Man) and whose securities are not admitted to trading on a regulated market in the United Kingdom (or the Channel Islands or the Isle of Man) if the company is considered by the Panel on Takeovers and Mergers, or the Takeover Panel, to have its place of central management and control in the United Kingdom (or the Channel Islands or the Isle of Man). This is known as the “residency test.” The test for central management and control under the Takeover Code is different from that used by the U.K. tax authorities. Under the Takeover Code, the Takeover Panel will determine whether we have our place of central management and control in the United Kingdom by looking at various factors, including the structure of our Board of Directors, the functions of the directors and where they are resident.

If at the time of a takeover offer the Takeover Panel determines that we have our place of central management and control in the United Kingdom, we would be subject to a number of rules and restrictions, including but not limited to the following: (1) our ability to enter into deal protection arrangements with a bidder would be extremely limited; (2) we might not, without the approval of our shareholders, be able to perform certain actions that could have the effect of frustrating an offer, such as issuing shares or carrying out acquisitions or disposals; and (3) we would be obliged to provide equality of information to all bona fide competing bidders.

If we are a passive foreign investment company, U.S. investors in our ordinary shares could be subject to adverse U.S. federal income tax consequences.

The rules governing passive foreign investment companies, or PFICs, can have adverse effects for U.S. federal income tax purposes. The tests for determining PFIC status for a taxable year depend upon the relative values of certain categories of assets and the relative amounts of certain kinds of income. We do not believe that we are currently a PFIC, and we do not anticipate becoming a PFIC in the foreseeable future. Notwithstanding the foregoing, the determination of whether we are a PFIC depends on the particular facts and circumstances (such as the valuation of our assets, including goodwill and other intangible assets) and may also be affected by the application of the PFIC rules, which are subject to differing interpretations. The fair market value of our assets is expected to depend, in part, upon (a) the market price of our ordinary shares and (b) the composition of our income and assets, which will be affected by how, and how quickly, we spend any cash that is raised in any financing transaction. In light of the foregoing, no assurance can be provided that we are not currently a PFIC or that we will not become a PFIC in any future taxable year.

If we are a PFIC, U.S. holders of our ordinary shares would be subject to adverse U.S. federal income tax consequences, such as ineligibility for any preferred tax rates on capital gains or on actual or deemed dividends, interest charges on certain taxes treated as deferred, and additional reporting requirements under U.S. federal income tax laws and regulations. Whether or not U.S. holders of our ordinary shares make a timely qualified electing fund, or QEF, election or mark-to-market election may affect the U.S. federal income tax consequences to U.S. holders with respect to the acquisition, ownership and disposition of our ordinary shares and any distributions such U.S. holders may receive. Investors should consult their own tax advisors regarding all aspects of the application of the PFIC rules to our ordinary shares.

U.S. holders of 10% or more of the voting power of our ordinary shares may be subject to U.S. federal income taxation at ordinary income tax rates on undistributed earnings and profits.

There is a risk that we will be classified as a controlled foreign corporation, or CFC, for U.S. federal income tax purposes. We will generally be classified as a CFC if more than 50% of our outstanding shares, measured by reference to voting power or value, are owned (directly, indirectly or by attribution) by “U.S. Shareholders.” For this purpose, a “U.S. Shareholder” is any U.S. person that owns directly, indirectly or by attribution, 10% or more of the voting power of our outstanding shares. If we are classified as a CFC, a U.S. Shareholder may be subject to U.S. income taxation at ordinary income tax rates on all or a portion of our undistributed earnings and profits attributable to “subpart F income” and may also be subject to tax at ordinary income tax rates on any gain realized on a sale of ordinary shares, to the extent of our current and accumulated earnings and profits attributable to such shares. The CFC rules are complex and U.S. Shareholders of the ordinary shares are urged to consult their own tax advisors regarding the possible application of the CFC rules to them in their particular circumstances.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our U.K. corporate headquarters and operations, including our laboratory facility, are located in Abingdon, England, where we currently lease approximately 7,600 square feet of office space, 3,400 square feet of manufacturing space, 3,500 of laboratory space, and 2,800 square feet of storage/warehouse space. The leases on these facilities expire in 2019, with the exception of the storage/warehouse space which expires in 2018. Our current rents under these leases are \$306,000 annually for the office, \$131,000 annually for the manufacturing space, \$142,000 annually for the lab, and \$34,000 annually for the storage/warehouse space, each of which are subject to change.

Our U.S. corporate headquarters is located in Marlborough, Massachusetts, where we currently lease approximately 14,500 square feet of office space. The lease on this facility expires in 2018. Our current rent under this lease is \$273,000 annually, subject to annual increases. Our U.S. laboratory facility is located in Memphis, Tennessee, where we currently lease approximately 35,000 square feet of space. The lease on this facility expires in 2021. Our current rent under this lease is \$146,000 annually, subject to annual increases.

We believe that our current facilities are suitable and adequate to meet our current needs and that suitable additional or substitute space will be available to accommodate future growth of our business.

Item 3. Legal Proceedings

We are not currently a party to any pending legal proceedings that we believe will have a material adverse effect on our business or financial condition. However, we may be subject to various claims and legal actions arising in the ordinary course of business from time to time.

Item 4. Mine Safety Disclosures

Not applicable.

PART II**Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities****Market Information**

Our ordinary shares trade on the NASDAQ Global Market under the symbol "OXFD." Our ordinary shares were initially listed on November 22, 2013. The price range per share reflected in the table below is the high and low sales prices of our ordinary shares as reported by NASDAQ (rounded to the nearest penny) for the period presented.

	Year ended December 31, 2014		Year ended December 31, 2013*	
	High	Low	High	Low
First quarter	\$ 25.38	\$ 17.25	N/A	N/A
Second quarter	21.25	16.00	N/A	N/A
Third quarter	18.09	12.47	N/A	N/A
Fourth quarter	15.61	10.01	20.06	13.58

* From inception on November 22, 2013.

Shareholders

On March 2, 2015, there were 10 shareholders of record of our ordinary shares. This number does not include shareholders for whom shares were held in a "nominee" or "street" name. On March 2, 2015, the last reported sale price per share of our ordinary shares on The NASDAQ Global Market was \$14.44.

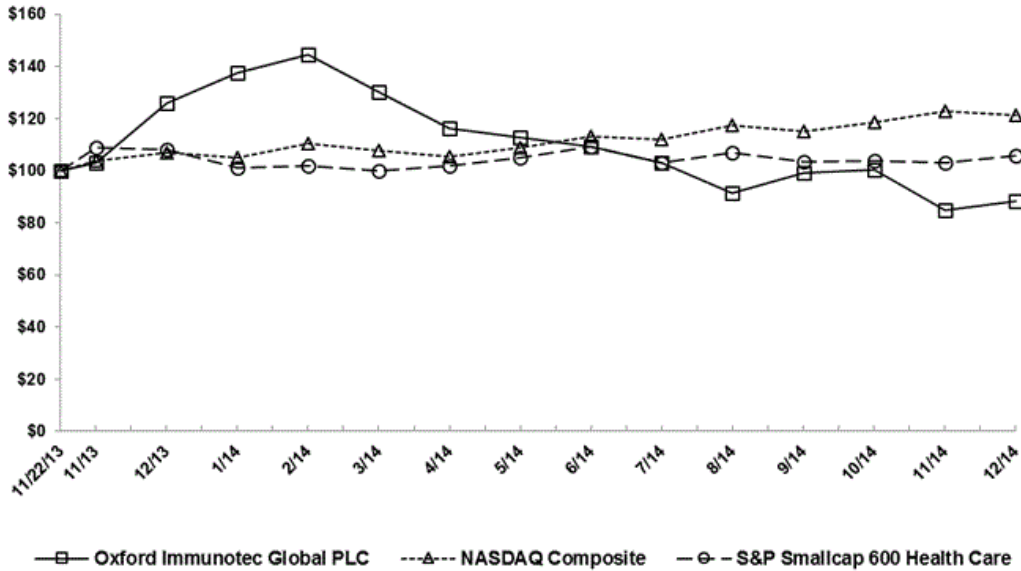
Dividends

We have never declared or paid cash dividends on our ordinary shares. We currently intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination as to the declaration and payment of dividends, if any, will be made at the discretion of our Board of Directors and will depend on then existing conditions, including our results of operations, financial conditions, contractual restrictions, capital requirements, business prospects and other factors our Board of Directors may deem relevant. Under English law, we may pay dividends only out of our accumulated, realized profits, so far as not previously utilized by distribution or capitalization, less our accumulated, realized losses, so far as not previously written off in a reduction or reorganization of capital duly made. Because we are a holding company and have no direct operations, we will only be able to pay dividends from our available cash on hand and any funds we receive from our subsidiaries.

[Table Of Contents](#)

The following graph compares the cumulative total shareholder return on our ordinary shares with that of the Nasdaq Composite Index and the S&P Smallcap 600 Healthcare Index. The comparison assumes that \$100.00 was invested at the close of market on November 22, 2013 in our ordinary shares or on October 31, 2013 in the Nasdaq Composite Index and the S&P Smallcap 600 Healthcare Index, and assumes reinvestment of dividends, if any. The performance graph is based on historical results and is not intended to suggest future performance.

COMPARISON OF CUMULATIVE TOTAL RETURN*
Among Oxford Immunotec Global PLC, the NASDAQ Composite Index
and the S&P Smallcap 600 Health Care Index



*\$100 invested on 11/22/13 in ordinary shares or 10/31/13 in index, including reinvestment of dividends. Fiscal year ending December 31.

This performance graph is being furnished pursuant to SEC rules and will not be incorporated by reference into any filing under the Securities Act or the Exchange Act except to the extent we specifically incorporate it by reference.

Recent Sale of Unregistered Securities

Financing transactions.

In November 2013, prior to closing of the Company’s initial public offering, the Company undertook a 1 for 6.705 reverse share split of its outstanding ordinary shares, which resulted in a proportional decrease in the number of ordinary shares outstanding as well as appropriate adjustments to outstanding A ordinary shares, preferred ordinary shares, warrants and options. After the reverse share split and immediately prior to the Company’s IPO, all outstanding preferred ordinary shares converted into ordinary shares. The nominal value of the ordinary shares was adjusted from £0.001 to £0.006705 per share. Prior period share and per share amounts have been adjusted to reflect the reverse share split.

In October 2013, the Company issued a convertible promissory note in the amount of \$5.0 million to Fosun Industrial Co., Ltd., (the Fosun Note). The Fosun Note paid interest at 8% per annum.

[Table Of Contents](#)

In the event of an IPO, the Fosun Note principal and accrued interest would automatically convert to ordinary shares at a 10% discount to the IPO offering price. Fosun also had an option to elect, prior to July 1, 2014, to require the Company to create and then convert the Fosun Note to H preferred ordinary shares or pay in full all principal and interest outstanding on or before July 1, 2016. In the event of an IPO, the shares would be subjected to restrictions prohibiting sale or transfer of more than one-third of the shares each year for the first three years following the offering.

The feature which required automatic conversion upon an IPO was a redemption feature that met the definition of an embedded derivative requiring bifurcation from the Fosun Note. The Company determined there was no initial fair market value of the liability.

In connection with the Company's IPO in November 2013, the Fosun Note and interest of approximately \$50,000 converted into 467,551 of the Company's ordinary shares at a price per share which reflected a 10% discount to the IPO offering price of \$12.00 per share. Upon conversion of the Fosun Note to ordinary shares, the derivative liability terminated. In connection with the IPO the Company marked the embedded derivative to market and recorded a \$561,000 loss on the change in the fair value of the instrument.

As of January 2013, we had issued 2,469,747 Series G preferred ordinary shares at a price of \$11.40 per share for aggregate consideration of approximately \$28 million to certain of our shareholders, including each of the investment funds identified in the section under the heading "Principal shareholders," in our registration statement on Form S-1 (File No. 333-191737), whom we refer to collectively as our "institutional investors," and Mr. Sandberg. The issuance occurred in two tranches; in June 2012, we issued 1,503,330 G preferred ordinary shares and in January 2013, we issued 966,417 G preferred ordinary shares.

In February 2012, we entered into a convertible loan facility, pursuant to which we borrowed an aggregate of \$4 million from certain of our shareholders. In connection with this loan facility, we issued 61,296 ordinary shares and 183,896 F preferred ordinary shares to the lenders as payment for a facility fee associated with the loan. As of June 2012, all lenders had converted their notes into G preferred ordinary shares in connection with the financing described above.

Beginning in 2009, we consummated a series of financing transactions that involved the issuance of ordinary shares and F preferred ordinary shares for a total of \$26 million. The financing occurred in three tranches, with the first tranche closing in July 2009. The second tranche occurred in April 2010 and, in connection therewith, we issued a total of 275,849 ordinary shares and 827,547 F preferred ordinary shares at a price per unit (consisting of one-third of an ordinary share and one F preferred ordinary share) of \$10.876, for aggregate consideration of \$9 million to certain of our shareholders. The third tranche occurred in February 2011 and, in connection therewith, we issued 306,499 ordinary shares and 919,497 F preferred ordinary shares at a price per unit (consisting of one-third of an ordinary share and one F preferred ordinary share) of \$10.876, for aggregate consideration of \$10 million.

These issuances were exempt from registration under the Securities Act pursuant to Rule 506 or Section 4(a)(2) as transactions by an issuer not involving any public offering.

Warrants.

In 2013, we issued a warrant to purchase 15,791 shares at \$0.80 per share to a lender in connection with a credit facility. That warrant expires May 25, 2023. In 2012, we issued a warrant to purchase 3,682 shares at \$0.07 per share to a lender in connection with a credit facility. That warrant expires on February 2, 2019.

These issuances were exempt from registration under the Securities Act pursuant to Rule 506 or Section 4(a)(2) as transactions by an issuer not involving any public offering.

Option grants and exercises.

From January 1, 2013 through December 31, 2013, we granted options to purchase a total of 312,198 ordinary shares to employees at a weighted-average price of \$5.12 per share. During the same period, we issued 201,459 ordinary shares upon the exercise of options to purchase such shares at a weighted-average price of \$0.12 per share.

In 2012, we granted options to purchase a total of 686,125 ordinary shares to employees at a weighted-average price of \$0.60 per share. During the same period, we issued 9,378 ordinary shares upon the exercise of options to purchase such shares at a weighted-average price of \$0.13 per share.

In 2011, we granted options to purchase a total of 53,740 ordinary shares to employees at a weighted-average price of \$0.25 per share. During the same period, we issued 4,459 ordinary shares upon the exercise of options to purchase such shares at a weighted-average price of \$0.10 per share.

From October 1, 2010 to December 31, 2010, we granted options to purchase a total of 60,752 ordinary shares to employees at a weighted-average price of \$0.27 per share. During the same period, we issued 447 ordinary shares upon the exercise of options to purchase such ordinary shares at a weighted-average price of \$0.11 per share.

These option grants and the issuances of ordinary shares upon exercise of such options were exempt from registration under the Securities Act pursuant to Rule 701 and Section 4(a)(2) as transactions by an issuer pursuant to certain compensatory benefit plans and not involving any public offering.

Scheme of arrangement.

On October 2, 2013, our equity holders exchanged their equity interests in Oxford Immunotec Limited for equity interests in Oxford Immunotec Global PLC pursuant to a Scheme of Arrangement under the laws of England and Wales. The issuance was an exchange transaction exempt from registration under the Securities Act pursuant to Section 3(a)(10).

Item 6. Selected Consolidated Financial Data

The following tables summarize our consolidated financial and other data. The consolidated statements of operations data for the years ended December 31, 2014, 2013 and 2012 and the consolidated balance sheet data as of December 31, 2014 and 2013 have been derived from our audited consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K. We derived the consolidated statements of operations data for the year ended December 31, 2011 and the consolidated balance sheet data as of December 31, 2012 and 2011 from our audited consolidated financial statements not included in this Annual Report on Form 10-K. We derived the consolidated statement of operations data for the year ended December 31, 2010 and the consolidated balance sheet data as of December 31, 2010 from our unaudited consolidated financial statements not included in this Annual Report on Form 10-K.

On October 2, 2013, we completed a scheme of arrangement under the laws of England and Wales, or the Scheme of Arrangement, which was approved by the High Court of Justice in England and Wales. Prior to the Scheme of Arrangement, our business was conducted by Oxford Immunotec Limited and its consolidated subsidiaries. Following the Scheme of Arrangement, our business has been conducted by Oxford Immunotec Global PLC and its consolidated subsidiaries, including Oxford Immunotec Limited.

We have prepared the unaudited consolidated financial information presented below on the same basis as our audited consolidated financial statements. The unaudited consolidated financial information includes all adjustments, consisting only of normal recurring adjustments that are necessary for a fair presentation of our financial position and results of operations for these periods. Our historical results are not necessarily indicative of the results that may be expected in the future. You should read the following selected financial data together with "Management's discussion and analysis of financial condition and results of operations" and our financial statements and accompanying notes included elsewhere in this Annual Report on Form 10-K. The selected financial data in this section are not intended to replace our financial statements and the accompanying notes.

(in thousands, except share and per share data) (unaudited)	Year ended December 31,				
	2014	2013 (1)	2012	2011	2010
Consolidated statement of operations data:					
Revenue	\$ 49,505	\$ 38,784	\$ 20,685	\$ 12,641	\$ 7,741
Cost of revenue	24,009	18,600	12,424	8,417	4,871
Gross profit	25,496	20,184	8,261	4,224	2,870
Operating expenses:					
Research and development	7,033	2,146	1,947	1,780	1,938
Sales and marketing	25,487	13,270	11,177	10,536	9,375
General and administrative	14,837	12,119	8,068	5,232	5,050
Total operating expenses	47,357	27,535	21,192	17,548	16,363
Loss from operations	(21,861)	(7,351)	(12,931)	(13,324)	(13,493)
Other income (expense)	(159)	(1,221)	(2,103)	101	1,500
Loss before income taxes	(22,020)	(8,572)	(15,034)	(13,223)	(11,993)
Income tax expense (benefit)	154	92	(151)	(119)	(147)
Net loss	\$ (22,174)	\$ (8,664)	\$ (14,883)	\$ (13,104)	\$ (11,846)
Net loss per share attributable to ordinary shareholders, basic and diluted	\$ (1.28)	\$ (2.26)	\$ (8.44)	\$ (10.78)	\$ (14.76)
Weighted-average shares used to compute net loss attributable to ordinary shareholders, basic and diluted	17,310,148	3,830,837	1,763,728	1,215,532	802,561
Supplemental financial metric:					
Adjusted EBITDA (2)	\$ (17,664)	\$ (6,008)	\$ (12,131)	\$ (12,519)	\$ (11,019)

- (1) Net loss includes \$1.9 million of accounting and auditing costs related to our registration statement on Form S-1, filed in connection with our IPO, as described in Note 1 "Description of business and significant accounting policies – Initial public offering, reorganization, reverse share split and conversion," to the Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K.
- (2) Adjusted EBITDA is a non-Generally Accepted Accounting Principles, or non-GAAP, financial measure that we calculate as profit (loss), adjusted for tax expense (benefit), interest expense, net, depreciation and amortization, share-based compensation, unrealized exchange fluctuations, loss on change in fair value of warrants, loss on change in fair value of derivative instrument, and change in fair value of contingent purchase price consideration. We believe that Adjusted EBITDA provides useful information to investors and analysts in understanding and evaluating our operating results in the same manner as our management and Board of Directors. Our presentation of Adjusted EBITDA is not made in accordance with U.S. GAAP, and our computation of Adjusted EBITDA may vary from others in the industry. Our use of Adjusted EBITDA has limitations as an analytical tool, and you should not consider it in isolation or as a substitute for analysis of our results as reported under U.S. GAAP. For example, Adjusted EBITDA does not reflect the impact of earnings or charges resulting from matters that we consider not to be indicative of our ongoing operations.

	As of December 31,				
	2014	2013	2012	2011	2010
Consolidated Balance Sheet Data:					
Cash and cash equivalents	\$ 50,165	\$ 76,494	\$ 12,578	\$ 2,334	\$ 6,644
Total assets	73,849	92,744	25,483	9,639	11,547
Total liabilities	13,240	11,992	8,534	4,413	3,371
Total shareholders' equity	60,609	80,752	16,949	5,226	8,176
Shares outstanding:					
Preferred ordinary shares	—	—	7,301,371	5,614,128	4,694,631
Ordinary shares	17,614,650	17,255,267	2,153,974	1,266,544	955,460

[Table Of Contents](#)

The following table presents a reconciliation of net loss, the most comparable U.S. GAAP financial measure, to Adjusted EBITDA for each of the periods indicated:

**Reconciliation of net loss to Adjusted EBITDA
(unaudited)**

(in thousands)	Year Ended December 31,				
	2014	2013	2012	2011	2010
Reconciliation of net loss to adjusted EBITDA					
Net loss	\$ (22,174)	\$ (8,664)	\$ (14,883)	\$ (13,104)	\$ (11,846)
Income tax expense (benefit)	154	92	(151)	(119)	(147)
Interest expense, net	52	328	1,477	3	18
Depreciation and amortization	1,742	1,101	801	630	586
EBITDA	(20,226)	(7,143)	(12,756)	(12,590)	(11,389)
Reconciling items:					
Share-based compensation expense	2,521	140	79	125	261
Unrealized exchange (gains) losses	(53)	155	546	(54)	109
Loss on change in fair value of warrants	22	279	—	—	—
Loss on change in fair value of derivative instrument	—	561	—	—	—
Change in fair value of contingent purchase price consideration	72	—	—	—	—
Adjusted EBITDA	\$ (17,664)	\$ (6,008)	\$ (12,131)	\$ (12,519)	\$ (11,019)

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our consolidated financial statements and the related notes to those statements included elsewhere in this Annual Report on Form 10-K. In addition to our historical consolidated financial information, the following discussion contains forward-looking statements that reflect our plans, estimates, beliefs and expectations. Our actual results and the timing of events could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this Annual Report on Form 10-K, particularly in Part I, Item 1A, "Risk Factors."

Overview

We are a global, commercial-stage diagnostics company focused on developing and commercializing proprietary tests for the management of immune-regulated conditions. Our proprietary T-SPOT technology platform allows us to measure the responses of specific immune cells to inform the diagnosis, prognosis and monitoring of patients with immune-regulated conditions. Our current development activities are principally focused on four areas: chronic infections, transplantation, autoimmune and inflammatory disease and immune-oncology. We believe these areas are particularly attractive for the development of diagnostic tests because they involve large patient populations and chronic conditions that present the opportunity for both initial diagnosis and additional testing to monitor the conditions. These immune-regulated conditions also tend to be characterized by wide variation in presentation and progression and often require expensive therapies, making diagnostic tests that can better categorize patients and inform treatment pathways particularly useful. We believe the sensitivity of our T-SPOT technology platform, which can measure T cell and innate immune cell responses at a single cell level, well position us to bring new insights into the diagnosis, prognosis and monitoring of immune-regulated conditions.

The initial product we have developed using our T-SPOT technology platform is our T-SPOT.*TB* test, which is used to test for Tuberculosis (TB) infection. Our T-SPOT.*TB* test has been approved for sale in over 50 countries, including the United States, where we have received PMA from the FDA, in Europe, where we have obtained a CE mark, as well as in Japan and China. Our T-SPOT.*TB* test has been included in clinical guidelines for TB screening in at least 17 countries, including the United States, several European countries and Japan. In addition, we have established reimbursement for our test in the United States, as well as a CPT code that is unique to our test. Outside the United States, we have established reimbursement in several countries where reimbursement applies, including Japan, Switzerland and Germany. We have also established the cost-effectiveness of our test in several published studies.

We have seven active development programs pertaining to new potential tests. Each program seeks to exploit our T cell or innate immune measuring technology, and these programs cover each of our four focus areas.

Our most advanced product in development leverages our T-SPOT technology platform to assess the strength of a patient's cellular immune response to CMV infection, assisting clinicians with monitoring anti-viral prophylaxis and evaluating patients at risk from CMV disease. We expect to complete development of our T-SPOT.*CMV* assay as an LDT in the United States, and to CE mark the test in Europe, in the first half of 2015. We are currently conducting two pivotal clinical studies to provide the evidence needed to drive adoption and acceptance by the medical and payor communities of this test. We expect to have the results of these studies in 2016.

Our second product in development is our T-SPOT.*PRT* (Panel of Reactive T-cells) test. This test, also based on our T-SPOT technology platform, assesses T cell responses to foreign tissue as a means of better informing organ rejection risk in current or potential transplant recipients. We expect to complete development of our T-SPOT.*PRT* assay as an LDT in the United States, and to CE mark the test in Europe, in the second half of 2015. We are currently conducting a pivotal clinical study to provide the evidence needed to drive adoption and acceptance by the medical and payor communities of this test. We expect to have the results of this study in 2017.

Our development pipeline also includes an assay to assess the overall competence of a transplant patient's immune system, products targeting autoimmune and inflammatory diseases, such as gout and Lyme disease, as well as informing the efficacy of biologic therapies; and a program to explore applications of our T-SPOT technology platform in the immune-oncology space. These products are in earlier stages of development.

We have incurred significant losses from inception and as of December 31, 2014 had an accumulated deficit of \$121.8 million. We anticipate that our operating losses will continue for the next few years as we continue to invest to grow our customer base and invest in research and development to expand our product portfolio. Our revenue for the year ended December 31, 2014 was \$49.5 million, for the year ended December 31, 2013 was \$38.8 million, and for the year ended December 31, 2012 was \$20.7 million. Our net loss for the year ended December 31, 2014 was \$22.2 million, for the year ended December 31, 2013 was \$8.7 million, and for the year ended December 31, 2012 was \$14.9 million.

On October 2, 2013, we completed a Scheme of Arrangement, which was approved by the High Court of Justice in England and Wales. Prior to the Scheme of Arrangement, our business was conducted by Oxford Immunotec Limited and its consolidated subsidiaries. Following the Scheme of Arrangement, our business has been conducted by Oxford Immunotec Global PLC and its consolidated subsidiaries, including Oxford Immunotec Limited. The financial information presented in this Annual Report on Form 10-K includes the results of Oxford Immunotec Limited and its consolidated subsidiaries for the period prior to the completion of the Scheme of Arrangement, as well as the results of Oxford Immunotec Global PLC and its consolidated subsidiaries for the period after completion of the Scheme of Arrangement.

[Table Of Contents](#)

On November 21, 2013, our initial public offering, or IPO, was declared effective by the Securities and Exchange Commission. Net proceeds from the IPO were approximately \$63.9 million, after deducting underwriting discounts and commissions and estimated offering expenses.

On July 31, 2014, we acquired substantially all of the assets of Boulder Diagnostics, Inc., or Boulder, a privately owned company developing immunology-based assays for autoimmune and inflammatory conditions/diseases. The assets acquired primarily relate to assays for Lyme disease and gout, and an assay to inform the efficacy of biologic therapies. Each product opportunity has the potential to address key unmet clinical needs and is well suited to the Company's growing commercial infrastructure. As part of the transaction, Boulder transferred to us all shares of capital stock in its wholly-owned subsidiary, Boulder Diagnostics Europe GmbH, such that the Company has become the sole owner of Boulder Diagnostics Europe GmbH.

There can be no assurance that we will be able to successfully develop and complete the development or commercialization of the products that we acquired in the Boulder acquisition. Further, even if we are able to profitably commercialize the underlying product candidates, there is no guarantee that we will be able to do so before any competitors develop and commercialize similar products.

Subsequent events

On January 29, 2015, we entered into an underwriting agreement (the "Underwriting Agreement") with J.P. Morgan Securities LLC and Piper Jaffray & Co., as representatives of the several underwriters named therein (collectively, the "Underwriters"), relating to the public offering (the "Offering") of 4,255,319 ordinary shares, nominal value £0.006705 (the "Shares"), at an offering price to the public of \$11.75 per Share (the "Offering Price"). The Underwriters agreed to purchase the Shares from us pursuant to the Underwriting Agreement at a price of \$11.045 per share. Under the terms of the Underwriting Agreement, we granted the Underwriters a 30-day option to purchase up to an additional 638,297 Shares (the "Option Shares") at the Offering Price, less underwriting discounts and commissions. On January 30, 2015, the Underwriters exercised their option to purchase the Option Shares in full. The gross proceeds to us from the sale of the Shares and the Option Shares were approximately \$57.5 million and we received net proceeds of approximately \$53.7 million after deducting underwriting discounts and commissions and estimated aggregate offering expenses payable by us. The Offering closed on February 4, 2015.

Effective January 15, 2015, the Remuneration Committee of the Board of Directors approved grants to employees for up to 355,509 share options from the Oxford Immunotec Global PLC 2013 Share Incentive Plan. These grants were issued to employees in the first quarter of 2015.

Financial operations overview

Revenue

We generate revenue from sales associated with our T-SPOT technology platform via our direct sales force and also through distributors. Our T-SPOT.TB test is our first commercialized product based on this platform.

Revenue mix

We currently offer our T-SPOT.TB test in either an *in vitro* diagnostic kit or a service format. In the former, we sell test kits and associated accessories to distributors for resale and directly to institutions and laboratories that perform TB testing. In the latter, we have established clinical testing laboratories in the United States and the United Kingdom, where we perform our T-SPOT.TB test on samples sent to us by customers. In these markets, we have found that many customers prefer to send samples to us rather than perform their own analysis on-site.

Our U.S. business derived 96%, 96% and 95% of revenue from our service offering (as opposed to diagnostic kit sales) for the years ended December 31, 2014, 2013 and 2012, respectively, which reflects our experience that U.S. customers prefer to send interferon-gamma release assay, or IGRA, tests out for processing and analysis rather than run them in-house. For the majority of our U.S. customers in the hospital and public health segments, TB testing programs are funded primarily from institutional budgets. We receive payment from these customers according to our pre-negotiated prices. For other segments of the U.S. market (notably, for example, the physicians' office segment), third-party reimbursement is often available to cover the cost of our T-SPOT.TB test.

[Table Of Contents](#)

Outside the United States, we derived 91%, 90% and 83% of our revenue from the sale of our *in vitro* diagnostic kits and associated accessories for the years ended December 31, 2014, 2013 and 2012, respectively. For the majority of our customers outside the United States, we primarily negotiate pricing directly with our customers; our prices are influenced to some degree by the mechanism and level of funding our customers receive for performing tests for TB infection.

(in thousands)	Year ended December 31,		
	2014	2013	2012
Revenue			
Product	\$ 25,407	\$ 19,905	\$ 9,080
Service	24,098	18,879	11,605
Total revenue	<u>\$ 49,505</u>	<u>\$ 38,784</u>	<u>\$ 20,685</u>

Revenue by geography

We market our T-SPOT.TB test through our own sales force in the United States, certain European countries and Japan. We sell through distributors in other parts of the world. As a result, our revenue is denominated in multiple currencies. We intend to expand our sales force globally and establish additional distributor relationships outside of our direct markets to better access international markets.

The following table reflects product revenue by geography (United States, Europe and rest of world, or Europe & ROW, and Asia) and as a percentage of total product revenue, based on the billing address of our customers.

(in thousands, except percentages)	Year ended December 31,					
	2014		2013		2012	
Revenue						
United States	\$ 22,537	46%	\$ 17,345	45%	\$ 10,366	50%
Europe & ROW	7,219	14%	7,157	18%	6,530	32%
Asia	19,749	40%	14,282	37%	3,789	18%
Total revenue	<u>\$ 49,505</u>	<u>100%</u>	<u>\$ 38,784</u>	<u>100%</u>	<u>\$ 20,685</u>	<u>100%</u>

In 2014, we created new subsidiaries in Hong Kong and Shanghai, further expanding our presence in Asia.

Diagnostic products such as ours are subject to periodic re-registration in China. We completed the re-registration process for our T-SPOT.TB test with the China Food and Drug Administration (CFDA) effective December 11, 2014. The registration will remain in effect until 2019.

Cost of revenue and operating expenses

Cost of revenue and gross margin

Cost of revenue consists of direct labor expenses, including employee benefits and share-based compensation expenses, overhead expenses, material costs, cost of laboratory supplies, freight costs, royalties paid under license agreements, U.S. medical device excise tax and depreciation of laboratory equipment and leasehold improvements. During the years ended December 31, 2014, 2013 and 2012, our cost of revenue represented 49%, 48% and 60%, respectively, of our total revenue.

(in thousands)	Year ended December 31,		
	2014	2013	2012
Cost of revenue			
Product	\$ 11,225	\$ 8,475	\$ 4,329
Service	12,784	10,125	8,095
Total cost of revenue	<u>\$ 24,009</u>	<u>\$ 18,600</u>	<u>\$ 12,424</u>

Our gross profit represents total revenue less total cost of revenue, and gross margin is gross profit expressed as a percentage of total revenue. Our gross margins were 52%, 52% and 40%, respectively, for the years ended December 31, 2014, 2013 and 2012. We expect our overall cost of revenue to increase as we continue to increase our volume of kits manufactured and tests performed. However, we also believe that through these increased volumes, we can achieve certain efficiencies in our manufacturing and laboratory operations that could help maintain or improve our overall margins.

Research and development expenses

Our research and development efforts have historically focused on developing multiple new diagnostic tests that use our quantitative T-cell measurement technology, including assays that would help transplant physicians better manage patients at risk of rejection and infection. We have expanded our research and development efforts since our initial public offering in November 2013 and, with the Boulder acquisition, we are expanding our research and development efforts to include the development of immunology-based assays for autoimmune and inflammatory conditions/diseases.

[Table Of Contents](#)

Our research and development expenses include costs associated with performing research, development, clinical and regulatory activities and validating improvements to our technology and processes for the purposes of enhancing product performance. Research and development expenses include personnel-related expenses, including share-based compensation, fees for contractual and consulting services, clinical trial costs, travel costs, laboratory supplies, amortization, depreciation, rent, insurance, repairs and maintenance. In June 2014, we hired a Chief Medical Officer, or CMO. Since joining the Company, the CMO has supported the continued growth of our T-SPOT.TB business and expanded the team focused on the development of new products through management of clinical trial programs. In addition, we are expanding our research and development efforts in the U.K. and in Memphis, Tennessee. We expense all research and development costs as incurred.

During the years ended December 31, 2014, 2013 and 2012, our research and development expenses represented 14%, 6% and 9%, respectively, of our total revenue. The increase in 2014 primarily related to development project expenses related to our transplant program, to the hiring of personnel in the United States to support development programs and to new projects acquired in the Boulder acquisition.

Sales and marketing expenses

Our sales and marketing expenses include costs associated with our sales organization, including our direct sales force and sales management, and our marketing, customer service and business development personnel. These expenses consist principally of salaries, commissions, bonuses and employee benefits for these personnel, including share-based compensation, as well as travel costs related to sales, marketing, customer service activities, medical education activities and overhead expenses. We expense all sales and marketing costs as incurred.

We continue to expand our operations in Asia. During 2014, we established two new subsidiaries in Asia: Oxford Immunotec Asia Limited, located in Hong Kong, and Oxford Immunotec (Shanghai) Medical Device Co. Ltd., located in Shanghai. In addition, we are expanding our sales force in Japan.

During the years ended December 31, 2014, 2013 and 2012, our sales and marketing expenses represented 52%, 34% and 54%, respectively, of our total revenue. We expect our sales and marketing costs to increase, as we expand our sales force, business development activities, geographic presence, and marketing and medical education programs to increase awareness and adoption of our current T-SPOT.TB test and future products.

General and administrative expenses

Our general and administrative expenses include costs for our executive, accounting and finance, legal, information technology, or IT, and human resources functions. These expenses consist principally of salaries, bonuses and employee benefits for the personnel included in these functions, including share-based compensation and travel costs, professional services fees, such as consulting, audit, tax and legal fees, costs related to our Board of Directors, general corporate costs, overhead expenses, and bad debt expense. We expense all general and administrative expenses as incurred.

During the years ended December 31, 2014, 2013 and 2012, our general and administrative expenses represented 30%, 31% and 39%, respectively, of our total revenue. Our general and administrative expenses have increased primarily due to the costs of operating as a public company, such as additional legal, accounting and finance, and corporate governance expenses, including expenses related to compliance with the Sarbanes-Oxley Act, directors' and officers' insurance premiums, and investor relations expenses.

Other income (expense)

Other income (expense) includes interest expense, net, foreign exchange losses, and other income and expense items.

Monetary assets and liabilities that are denominated in foreign currencies are remeasured at the period-end closing rate with resulting unrealized exchange fluctuations. Realized exchange fluctuations result from the settlement of transactions in currencies other than the functional currencies of our businesses. The functional currencies of our businesses are U.S. Dollars, Pounds Sterling, Euros and Yen, depending on the entity.

Results of operations

Comparison of years ended December 31, 2014 and 2013

The following table sets forth, for the periods indicated, the amounts of certain components of our statements of operations and the percentage of total revenue represented by these items, showing period-to-period changes.

(in thousands, except percentages)	Year ended December 31,				Change	
	2014		2013			
	Amount	% of revenue	Amount	% of revenue	Amount	%
Revenue:						
Product	\$ 25,407	51%	\$ 19,905	51%	\$ 5,502	28%
Service	24,098	49%	18,879	49%	5,219	28%
Total revenue	49,505	100%	38,784	100%	10,721	28%
Cost of revenue:						
Product	11,225	23%	8,475	22%	2,750	32%
Service	12,784	26%	10,125	26%	2,659	26%
Total cost of revenue	24,009	48%	18,600	48%	5,409	29%
Gross profit	25,496	52%	20,184	52%	5,312	26%
Operating expenses:						
Research and development	7,033	14%	2,146	6%	4,887	228%
Sales and marketing	25,487	51%	13,270	34%	12,217	92%
General and administrative	14,837	30%	12,119	31%	2,718	22%
Total operating expenses	47,357	96%	27,535	71%	19,822	72%
Loss from operations	(21,861)	(44)%	(7,351)	(19)%	(14,510)	197%
Interest expense, net	(52)	0%	(328)	(1)%	276	(84)%
Foreign exchange losses	(352)	(1)%	(423)	(1)%	71	(17)%
Other income (expense)	245	0%	(470)	(1)%	715	(152)%
Loss before income taxes	(22,020)	(44)%	(8,572)	(22)%	(13,448)	157%
Income tax expense (benefit)	154	0%	92	0%	62	67%
Net loss	\$ (22,174)	(45)%	\$ (8,664)	(22)%	\$ (13,510)	156%

[Table Of Contents](#)

Revenue

Revenue increased by 28% to \$49.5 million for the year ended December 31, 2014 compared to \$38.8 million for the same period in 2013. This increase in revenue was due to an increase in volumes across all regions where we sell our T-SPOT.*TB* test. Asia revenue grew by 38%, to \$19.7 million, compared to the same period in 2013, due primarily to higher revenue in China and Japan. U.S. revenue grew by 30%, to \$22.5 million, compared to the same period in 2013, driven by growth of \$2.5 million from the addition of new customers and \$2.7 million from existing customers. Europe & ROW revenue grew by 1%, to \$7.2 million, compared to the same period in 2013.

(in thousands, except percentages)	Year ended December 31,		Change	
	2014	2013	Amount	%
Revenue				
Product	\$ 25,407	\$ 19,905	\$ 5,502	28%
Service	24,098	18,879	5,219	28%
Total revenue	\$ 49,505	\$ 38,784	\$ 10,721	28%

(in thousands, except percentages)	Year ended December 31,		Change	
	2014	2013	Amount	%
Revenue				
United States	\$ 22,537	\$ 17,345	\$ 5,192	30%
Europe & ROW	7,219	7,157	62	1%
Asia	19,749	14,282	5,467	38%
Total revenue	\$ 49,505	\$ 38,784	\$ 10,721	28%

Cost of revenue and gross margin

Cost of revenue increased by 29% to \$24.0 million for the year ended December 31, 2014 from \$18.6 million in the same period in 2013. This increase in cost of revenue was due to the increased volume of kits sold and an increase in volume of tests sold through our laboratories in the United States and the United Kingdom. Gross margin for 2014 was 51.5% compared to 52.0% for 2013. The decrease in gross margin was primarily due to currency effects, the impact of share-based compensation included in cost of revenue and investments to increase capacity in our service lab, offset by underlying improvements in reducing kit costs and streamlining service operations in our labs.

(in thousands, except percentages)	Year ended December 31,		Change	
	2014	2013	Amount	%
Cost of revenue				
Product	\$ 11,225	\$ 8,475	\$ 2,750	32%
Service	12,784	10,125	2,659	26%
Total cost of revenue	\$ 24,009	\$ 18,600	\$ 5,409	29%

Research and development expenses

Research and development expenses increased by 228% to \$7.0 million for the year ended December 31, 2014 from \$2.1 million for the same period in 2013. This increase was primarily related to development project expenses related to our transplant program and to the hiring of personnel in the United States to support development programs. In addition, with the acquisition of Boulder in the third quarter of 2014, we have expanded our research efforts to include assays for Lyme disease and gout and an assay to inform decisions regarding biologic therapies. In addition, we restructured the operations of Boulder to integrate them into our existing operations. This restructuring, which included the termination of 4 employees, the relocation of 3 employees, the closing of excess facilities, and related costs, resulted in a restructuring charge of \$182,000 that has been recorded in research and development expenses. As a percentage of total revenue, research and development expenses increased to 14% for the year ended December 31, 2014 from 6% for the same period in 2013.

Sales and marketing expenses

Sales and marketing expenses increased 92% to \$25.5 million for the year ended December 31, 2014 from \$13.3 million for the same period in 2013. The increase reflects an increase in sales personnel and in personnel-related costs for commissions on increased sales and for hiring of sales, marketing, administrative and technical support personnel. As a percentage of total revenue, sales and marketing expenses increased to 51% for the year ended December 31, 2014 from 34% for the same period in 2013.

[Table Of Contents](#)

General and administrative expenses

General and administrative expenses increased by 22% to \$14.8 million for the year ended December 31, 2014 from \$12.1 million for the same period in 2013. The increase reflects the increased regulatory costs of being a public company and increases in personnel-related costs associated with increases in our legal, accounting and finance, IT, corporate development and human resources headcount, and consulting costs to support our growth. As a percentage of total revenue, general and administrative expenses decreased to 30% for the year ended December 31, 2014 from 31% for the same period in 2013.

Interest expense, net

Interest expense, net was \$52,000 for the year ended December 31, 2014 as compared to \$328,000 in the same period in 2013. The 2014 expense consisted primarily of interest expense relating to the fit out of our Marlborough facility. The 2013 expense consisted primarily of interest expense on our term debt and revolving credit facilities. We repaid the borrowings under our credit facility with Comerica Bank in May 2013 and entered into a new term loan and revolving line of credit with Square 1 Bank. This loan was repaid and the credit facility cancelled in December 2013, following our IPO. See “– Liquidity and capital resources – Sources of funds – Credit facilities.”

Foreign exchange gains (losses)

We recorded foreign exchange losses of \$352,000 for the year ended December 31, 2014 as a net result of U.S. Dollar denominated bank accounts, accounts receivable, and accounts payable reflected on the books of Oxford Immunotec Limited, which has a functional currency of the U.K. Pound Sterling, as the Pound rose against the Dollar for the first six months of 2014 before falling in the second half of 2014. For the year ended December 31, 2013, we recorded foreign exchange losses of \$423,000 as a net result of U.S. Dollar denominated bank accounts, accounts receivable, accounts payable, and loans payable on the books of Oxford Immunotec Limited, as the Pound increased versus the Dollar. We are exposed to foreign exchange rate risk because we currently operate in three major regions of the world: the United States, Europe & ROW, and Asia, our revenue is denominated in multiple currencies. Approximately 46% of our sales were in the United States, which are denominated in U.S. Dollars. Sales in China are denominated in U.S. Dollars but these sales are made by our United Kingdom-based subsidiary where the Pound Sterling is the functional currency. As a result, these sales are subject to remeasurement into Pounds Sterling and then translation into U.S. Dollars when we consolidate our financial statements. Sales in Europe are denominated primarily in the Pound Sterling and Euro. As we grow Europe & ROW sales outside the United Kingdom and the Euro Zone, we may be subject to risk from additional currencies. Sales in Japan are denominated in Yen, and our sales in Japan, which started in late 2012, grew significantly in 2013 and have continued to grow in 2014.

Our expenses are generally denominated in the currencies in which our operations are located, which are primarily in the United States, the United Kingdom and Japan.

As we continue to grow our business outside the United States, our results of operations and cash flows will be subject to fluctuations due to changes in foreign currency exchange rates, which could harm our business in the future. To date, we have not entered into any foreign currency hedging contracts although we may do so in the future.

Other income (expense)

Other income was \$245,000 for the year ended December 31, 2014 as compared to other expense of \$470,000 in the same period in 2013. Other income in 2014 consisted largely of a \$149,000 U.K. research grant and an \$83,000 Tennessee FastTrack Job Training Assistance program. Other expense in 2013 consisted largely of a loss on the change in fair value of warrants.

Comparison of years ended December 31, 2013 and 2012

The following table sets forth, for the periods indicated, the amounts of certain components of our statements of operations and the percentage of total revenue represented by these items, showing period-to-period changes.

(in thousands, except percentages)	Year ended December 31,				Change	
	2013		2012		Amount	%
	Amount	% of revenue	Amount	% of revenue		
Revenue:						
Product	\$ 19,905	51%	\$ 9,080	44%	\$ 10,825	119%
Service	18,879	49%	11,605	56%	7,274	63%
Total revenue	38,784	100%	20,685	100%	18,099	87%
Cost of revenue:						
Product	8,475	22%	4,329	21%	4,146	96%
Service	10,125	26%	8,095	39%	2,030	25%
Total cost of revenue	18,600	48%	12,424	60%	6,176	50%
Gross profit	20,184	52%	8,261	40%	11,923	144%
Operating expenses:						
Research and development	2,146	6%	1,947	9%	199	10%
Sales and marketing	13,270	34%	11,177	54%	2,093	19%
General and administrative	12,119	31%	8,068	39%	4,051	50%
Total operating expenses	27,535	71%	21,192	102%	6,343	30%
Loss from operations	(7,351)	(19)%	(12,931)	(63)%	5,580	(43)%
Interest expense, net	(328)	(1)%	(1,477)	(7)%	1,149	(78)%
Foreign exchange losses	(423)	(1)%	(626)	(3)%	203	(32)%
Other expense	(470)	(1)%	—	0%	(470)	N/A
Loss before income taxes	(8,572)	(22)%	(15,034)	(73)%	6,462	(43)%
Income tax expense (benefit)	92	0%	(151)	(1)%	243	(161)%
Net loss	\$ (8,664)	(22)%	\$ (14,883)	(72)%	\$ 6,219	(42)%

[Table Of Contents](#)

Revenue

Revenue increased by 87% to \$38.8 million for the year ended December 31, 2013 compared to \$20.7 million for the same period in 2012. This increase in revenue was due to an increase in volumes across all the regions where we sell our test. U.S. revenue grew by 67% driven by growth of \$2.8 million from existing customers and \$4.2 million from the addition of new customers as a result of an increased focus on selling to larger institutional accounts. Asia revenue grew by \$10.5 million due to \$3.0 million higher revenue in China and \$7.5 million higher revenue in Japan where our T-SPOT.TB test was launched in the fourth quarter of 2012. We have seen significant demand for the test since its launch in Asia. Europe & ROW revenue growth was 10% over the same period in 2012.

(in thousands, except percentages)	Year ended December 31,		Change	
	2013	2012	Amount	%
Revenue				
Product	\$ 19,905	\$ 9,080	\$ 10,805	119%
Service	18,879	11,605	7,274	63%
Total revenue	<u>\$ 38,784</u>	<u>\$ 20,685</u>	<u>\$ 18,099</u>	<u>87%</u>

(in thousands, except percentages)	Year ended December 31,		Change	
	2013	2012	Amount	%
Revenue				
United States	\$ 17,345	\$ 10,366	\$ 6,979	67%
Europe & ROW	7,157	6,530	627	10%
Asia	14,282	3,789	10,493	277%
Total revenue	<u>\$ 38,784</u>	<u>\$ 20,685</u>	<u>\$ 18,099</u>	<u>87%</u>

Cost of revenue and gross margin

Cost of revenue increased by 50% to \$18.6 million for the year ended December 31, 2013 from \$12.4 million in the same period in 2012. This increase in cost of revenue was due to the increased volume of kits sold and an increase in volume of tests sold through our laboratories in the United States and the United Kingdom. Gross margin increased to 52% in 2013 from 40% in 2012. The gross margin improvement was attributable to a reduction in material costs per test and efficiency from increased volume in our manufacturing operations. In 2012, we incurred costs related to the start-up of our new laboratory in Memphis, Tennessee and in late 2012 and early 2013, we incurred extra costs related to running two labs. In the first quarter of 2013, we consolidated our U.S. laboratory operations in Memphis, Tennessee and closed our Marlborough, Massachusetts laboratory. Operating a single laboratory in the United States has already yielded significant operating leverage that has also led to improving margins.

(in thousands, except percentages)	Year ended December 31,		Change	
	2013	2012	Amount	%
Cost of revenue				
Product	\$ 8,475	\$ 4,329	\$ 4,146	96%
Service	10,125	8,095	2,030	25%
Total cost of revenue	<u>\$ 18,600</u>	<u>\$ 12,424</u>	<u>\$ 6,176</u>	<u>50%</u>

Research and development expenses

Research and development expenses increased by 10% to \$2.1 million for the year ended December 31, 2013 from \$1.9 million for the same period in 2012. This increase was primarily related to development project expenses and to the establishment of a technical team in the United States to improve processes efficiency and reduce costs in our U.S. laboratory operations. As a percentage of total revenue, research and development expenses decreased to 6% for the year ended December 31, 2013 from 9% for the same period in 2012.

Sales and marketing expenses

Sales and marketing expenses increased 19% to \$13.3 million for the year ended December 31, 2013 from \$11.2 million for the same period in 2012. The increase reflects an increase in sales personnel and in personnel-related costs for higher commissions on increased sales and for hiring of sales, marketing, administrative and technical support personnel in our office in Japan. As a percentage of total revenue, sales and marketing expenses decreased to 34% for the year ended December 31, 2013 from 54% for the same period in 2012.

[Table Of Contents](#)

General and administrative expenses

General and administrative expenses increased by 50% to \$12.1 million for the year ended December 31, 2013 from \$8.1 million for the same period in 2012. The increase was due to accounting and auditing costs in the third and fourth quarters of 2013 related to our public offering in the fourth quarter of 2013 and increases in personnel-related costs associated with increases in our legal, accounting and finance, IT, corporate development and human resources headcount, and consulting costs to support our growth. As a percentage of total revenue, general and administrative expenses decreased to 31% for the year ended December 31, 2013 from 39% for the same period in 2012.

Interest expense, net

Interest expense, net was \$0.3 million for the year ended December 31, 2013 as compared to \$1.5 million in the same period in 2012. The 2013 expense consisted primarily of interest expense on our term debt and revolving credit facilities. We repaid the borrowings under our credit facility with Comerica Bank in May 2013 and entered into a new term loan and revolving line of credit with Square 1 Bank. This loan was repaid and the credit facility cancelled in December 2013, following our IPO. The 2012 expense included interest on a revolving line of credit and a \$1.3 million loan discount that was recorded as interest expense, related to a 2012 convertible bridge loan agreement with then-existing investors.

Liquidity and capital resources

Sources of funds

Since our inception, we have incurred significant net losses and negative cash flows from operations. For the year ended December 31, 2014 we had a net loss of \$22.2 million and used \$20.8 million of cash for operating activities. As of December 31, 2014, we had an accumulated deficit of \$121.8 million. We incurred a net loss of \$8.7 million and used \$5.6 million of cash for operating activities for the year ended December 31, 2013.

As of December 31, 2014, we had cash and cash equivalents of \$50.2 million. In November 2013, we completed our initial public offering. Net proceeds from the IPO were approximately \$63.9 million.

Subsequent event

On January 29, 2015, we entered into an Underwriting Agreement with a group of Underwriters, relating to an Offering of 4,255,319 ordinary shares, nominal value £0.006705 (the "Shares"), at an Offering Price to the public of \$11.75 per Share. The Underwriters agreed to purchase the Shares from us pursuant to the Underwriting Agreement at a price of \$11.045 per share. Under the terms of the Underwriting Agreement, we granted the Underwriters a 30-day option to purchase up to an additional 638,297 Option Shares at the Offering Price, less underwriting discounts and commissions. On January 30, 2015, the Underwriters exercised their option to purchase the Option Shares in full. The gross proceeds to us from the sale of the Shares and the Option Shares were approximately \$57.5 million and we received net proceeds of approximately \$53.7 million after deducting underwriting discounts and commissions and estimated aggregate offering expenses payable by us. The Offering closed on February 4, 2015.

Credit facilities

In February 2012 we entered into a loan and security agreement with Comerica Bank that provided for borrowings through a credit facility of up to \$3.0 million initially through February 2013 and extended through May 2013. In February 2012, we borrowed \$1.5 million under the credit facility. Interest accrued daily on the outstanding balance at the prime rate plus 1.5%, with a minimum of the Daily Adjusting LIBOR rate plus 2.5% per annum. The loan was secured by substantially all of our assets. This loan was repaid in May 2013.

In May 2013, we entered into a new loan and security agreement with Square 1 Bank consisting of a term loan and a revolving line of credit. We used the loan proceeds to repay the loan from Comerica Bank. The Square 1 Bank loan was secured by substantially all of our assets. Tranche A of the term loan, which was borrowed at closing, was for \$6.0 million. The term loan was repaid and the revolving line of credit canceled in December 2013, following our IPO. The Company had no available credit facilities as of December 31, 2014.

Summary of cash flows

The following table summarizes our cash and cash equivalents, accounts receivable and cash flows for the periods indicated:

(in thousands)	As of and for the years ended	
	December 31,	
	2014	2013
Cash and cash equivalents, excluding restricted cash	\$ 50,165	\$ 76,494
Accounts receivable, net	6,823	4,754
Net cash used in operating activities	\$ (20,777)	\$ (5,619)
Net cash used in investing activities	(5,027)	(1,767)
Net cash (used in) provided by financing activities	(151)	70,699
Effect of exchange rate changes on cash and cash equivalents	(374)	603
Net (decrease) increase in cash and cash equivalents, excluding restricted cash	\$ (26,329)	\$ 63,916

Cash flows for the years ended December 31, 2014 and 2013*Operating activities*

Net cash used in operating activities was \$20.8 million during the year ended December 31, 2014, which included a net loss of \$22.2 million, non-cash items of \$4.3 million, and a net increase in operating assets less liabilities of \$2.9 million. The non-cash items consisted of share-based compensation expense of \$2.5 million, depreciation and amortization expense of \$1.7 million, and a \$22,000 loss on the change in fair value of warrants. We had a net cash outflow of \$2.9 million from changes in operating assets and liabilities during the period. The changes in operating assets and liabilities included an increase in accounts receivable of \$2.3 million, an increase in inventory of \$1.2 million, and an increase in prepaid expenses and other assets of \$594,000, partially offset by an increase in accounts payable and accrued liabilities of \$659,000, and an increase in deferred income of \$572,000. The increase in accounts receivable primarily reflects increased revenue during the year ended December 31, 2014, as well as the timing of receipts. Inventory has been increasing in anticipation of growing revenue and the increase in prepaid expenses and other assets reflects the timing of certain payments. The increase in accounts payable and accrued liabilities was largely due to the timing of payments. The increase in deferred income relates to the growth in sales to our Japanese importer.

Net cash used in operating activities was \$5.6 million during the year ended December 31, 2013, which included a net loss of \$8.7 million, non-cash items of \$2.1 million, and a net decrease in operating assets less liabilities of \$1.0 million. The non-cash items consisted of depreciation and amortization expense of \$1.1 million, a \$0.6 million loss on change in fair value of a derivative instrument, a \$0.3 million loss on change in fair value of warrants, and share-based compensation expense of \$0.1 million. We had a net cash inflow of \$1.0 million from changes in operating assets and liabilities during the period. The significant items in the changes in operating assets and liabilities included an increase in accounts payable and accrued liabilities of \$3.4 million, a decrease in accounts receivable of \$0.6 million, and an increase in deferred income of \$0.6 million, partially offset by an increase in inventory of \$2.8 million and an increase in prepaid expenses and other assets of \$0.9 million. The increase in accounts payable and accrued liabilities was primarily related to higher operating expenses due to growth in our business. The decrease in accounts receivable reflected the timing of significant payments from our Asian customers. The increase in deferred income related to the growth in sales to our Japanese importer. Inventory had been increasing in anticipation of growing revenue. The increase in prepaid expenses and other assets reflected increased value added tax (VAT) receivables in the United Kingdom and increased deferred cost of revenue due to increased sales in Japan.

Investing activities

Net cash used in investing activities was \$5.0 million and \$1.8 million for the years ended December 31, 2014 and 2013, respectively. The higher net cash used in the year ended December 31, 2014 related primarily to \$1.7 million used in the acquisition of Boulder, net of cash acquired. In addition, there was a \$1.2 million increase in purchases of property and equipment in the period compared to the same period in 2013, a \$168,000 decrease in the reduction in cash pledged as security in connection with our facilities leases in the year ended December 31, 2014 compared to the same period in 2013, and there was a \$149,000 increase in purchases of intangible assets.

Financing activities

Net cash used in financing activities was \$151,000 during the year ended December 31, 2014.

Net cash provided by financing activities was \$70.7 million during the year ended December 31, 2013, consisting primarily of \$63.9 million raised in our IPO, after deducting underwriting discounts and commissions, and offering expenses.

Cash flows for the years ended December 31, 2013 and 2012

Operating activities

Net cash used in operating activities was \$5.6 million during the year ended December 31, 2013, which included a net loss of \$8.7 million, non-cash items of \$2.1 million, and a net decrease in operating assets less liabilities of \$1.0 million. The non-cash items consisted of depreciation and amortization expense of \$1.1 million, a \$0.6 million loss on change in fair value of a derivative instrument, a \$0.3 million loss on change in fair value of warrants, and share-based compensation expense of \$0.1 million. We had a net cash inflow of \$1.0 million from changes in operating assets and liabilities during the period. The significant items in the changes in operating assets and liabilities included an increase in accounts payable and accrued liabilities of \$3.4 million, a decrease in accounts receivable of \$0.6 million, and an increase in deferred income of \$0.6 million, partially offset by an increase in inventory of \$2.8 million and an increase in prepaid expenses and other assets of \$0.9 million. The increase in accounts payable and accrued liabilities was primarily related to higher operating expenses due to growth in our business. The decrease in accounts receivable reflected the timing of significant payments from our Asian customers. The increase in deferred income related to the growth in sales to our Japanese importer. Inventory had been increasing in anticipation of growing revenue. The increase in prepaid expenses and other assets reflected increased value added tax (VAT) receivables in the United Kingdom and increased deferred cost of revenue due to increased sales in Japan.

Net cash used in operating activities was \$14.4 million during the year ended December 31, 2012, which included net loss of \$14.9 million and non-cash items of \$2.4 million and a net increase in operating assets less liabilities of \$1.9 million. The non-cash items consisted primarily of a \$1.4 million loan discount that was recorded as interest expense related to the 2012 convertible bridge note agreement, depreciation and amortization expense of \$0.8 million and share-based compensation expense of \$0.1 million. We also had a net cash outflow of \$1.9 million from changes in operating assets and liabilities during the period. The significant items in the changes in operating assets and liabilities included an increase in accounts receivable of \$3.1 million and an increase in inventory of \$1.0 million offset by an increase in accrued liabilities of \$1.6 million and an increase in deferred revenue of \$0.8 million. The increase in accounts receivable and inventory was due primarily to the growth in our revenue. The increase in accrued liabilities was primarily related to increases in accrued employee related expenses and accrued royalties. The increase in deferred revenue related to the growth in sales to our Japanese importer.

Investing activities

Net cash used in investing activities was \$1.8 million and \$1.9 million for the years ended December 31, 2013 and 2012, respectively. These amounts related primarily to purchases of property and equipment and intangible assets, and a change in restricted cash pledged as security in connection with our facilities leases.

Financing activities

Net cash provided by financing activities was \$70.7 million during the year ended December 31, 2013, consisting primarily of \$63.9 million raised in our IPO, after deducting underwriting discounts and commissions, and offering expenses.

Net cash provided by financing activities was \$26.2 million during the year ended December 31, 2012, consisting primarily of \$12.7 million in proceeds from the first tranche of the G preferred ordinary share financing, \$8.1 million of proceeds received in advance related to the second tranche of the G preferred ordinary share financing, \$4.0 million in proceeds from the 2012 convertible bridge notes and \$1.5 million from borrowings under the Comerica Bank loan.

Operating and capital expenditure requirements

We have not achieved profitability on a quarterly or annual basis since our inception and we expect to incur net losses in the future. We expect that our operating expenses will increase as we continue to invest to grow our customer base, expand our marketing and distribution channels, hire additional employees and increase product development expenditures. Additionally, as a public company, we incur significant audit, legal and other expenses. We believe that our existing capital resources will be sufficient to fund our operations for the next few years.

Our future capital requirements will depend on many factors, including:

- our ability to continue to penetrate our existing market and new markets in the United States;
- the costs and timing of further expansion of our sales and marketing efforts;
- our ability to penetrate existing markets outside the United States and enter and develop new geographies;
- the progress that we make in developing new products based on our platform technology;
- the percentage of sales that are reimbursed by payors and our ability to collect our accounts receivable;
- our ability to generate cash from operations; and
- the acquisition of businesses or technologies that we may undertake.

Contractual obligations

We have contractual obligations for non-cancelable facilities leases, equipment leases and purchase commitments. Purchase commitments include future minimum royalty, license, and exclusivity payments to be paid under our license agreements with third parties for access to certain technologies. The following table reflects a summary of our contractual obligations as of December 31, 2014.

(in thousands)	Payments due by period				
	Total	Less than 1 year	1-3 Years	3-5 Years	More than 5 years
Operating lease obligations	\$ 3,837	\$ 975	\$ 1,825	\$ 1,037	\$ —
License commitments	8,453	1,688	3,376	3,364	25
Purchase commitments	3,930	3,180	500	250	—
Total	<u>\$ 16,220</u>	<u>\$ 5,843</u>	<u>\$ 5,701</u>	<u>\$ 4,651</u>	<u>\$ 25</u>

Critical accounting policies and significant judgments and estimates

We have prepared our consolidated financial statements in accordance with U.S. GAAP. Our preparation of these consolidated financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, expenses and related disclosures at the date of the consolidated financial statements, as well as revenue and expenses during the reporting periods. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results could therefore differ materially from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 1 to our consolidated financial statements included in this Annual Report on Form 10-K, we believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our financial statements.

Revenue recognition and accounts receivable

We derive revenue from the sale of our T-SPOT.TB diagnostic test to a broad range of customers including hospitals, public health departments, commercial testing laboratories, importers and distributors. We offer our T-SPOT.TB test in either an *in vitro* diagnostic kit or a service format.

Revenue from tests is generally paid directly by the customer and is recognized on the accrual basis when the following revenue recognition criteria are met: (1) persuasive evidence that an arrangement exists; (2) the kit has been shipped or delivered or, in the case of tests performed in our laboratory, when final results have been reported to the customer; (3) the price is fixed or determinable; and (4) collectability is reasonably assured.

In the United States, we also generate revenue from payments that are received from a variety of third-party payors, including government programs (Medicare and Medicaid) and commercial insurance companies, each with different billing requirements. Revenue from tests paid by third-party payors is recognized on an accrual basis based on our historical collection experience.

For kits sold in Japan, we currently recognize revenue after delivery to the wholesaler and when the wholesaler dispatches kits to satisfy a firm order from its customer at which point our price becomes determinable.

Accounts receivable are primarily amounts due from hospitals, public health departments, commercial testing laboratories, distributors and universities in addition to third party payors such as commercial insurance companies (including managed care organizations), government programs (Medicare and Medicaid in the United States) and individual patients.

Accounts receivable are reported net of an allowance for uncollectible accounts. The process of estimating the collection of accounts receivable involves significant assumptions and judgments. Specifically, the accounts receivable allowance is based on management's analysis of current and past due accounts, collection experience in relation to amounts billed, channel mix, any specific customer collection issues that have been identified and other relevant information. Our provision for uncollectible accounts is recorded as bad debt expense and included in general and administrative expenses. Although we believe amounts provided are adequate, the ultimate amounts of uncollectible accounts receivable could be in excess of the amounts provided.

Income taxes

We account for income taxes under the asset and liability method, which requires, among other things, that deferred income taxes be provided for temporary differences between the tax basis of our assets and liabilities and their financial statement reported amounts. In addition, deferred tax assets are recorded for the future benefit of utilizing net operating losses, or NOLs, and research and development credit carryforwards. A valuation allowance is established when necessary to reduce deferred tax assets to the amount expected to be realized.

[Table Of Contents](#)

We follow the accounting guidance for uncertainties in income taxes, which prescribes a recognition threshold and measurement process for recording uncertain tax positions taken, or expected to be taken, in a tax return in the financial statements. Additionally, the guidance also prescribes the derecognition, classification, accounting in interim periods and disclosure requirements for uncertain tax positions. We accrue for the estimated amount of taxes for uncertain tax positions if it is more likely than not that we would be required to pay such additional taxes. An uncertain tax position will not be recognized if it has less than a 50% likelihood of being sustained. We did not have any accrued interest or penalties associated with any unrecognized tax positions, and there were no such interest or penalties recognized during the years ended December 31, 2014, 2013, or 2012.

Share-based compensation

Share-based compensation relates to grants of options to purchase ordinary shares and restricted shares. Currently, we maintain one share incentive plan pursuant to which we may grant options to purchase our ordinary shares, restricted shares, restricted share units, and other share-based awards to our employees, directors and officers. This incentive plan is called the Oxford Immunotec Global PLC 2013 Share Incentive Plan, or the 2013 Plan. In addition, we maintain the 2008 Amended and Restated Stock Incentive Plan, or the 2008 Plan. No new share grants or awards will be made under the 2008 Plan.

We measure the cost of equity-settled transactions with employees by reference to the fair value of the equity instruments at the date on which they are granted. Estimating fair value for options requires determining the most appropriate valuation model, which is dependent on the terms and conditions of the grant. This estimate also requires determining the most appropriate inputs to the valuation model, including the expected life of the award, volatility and dividend yield, and making certain assumptions about the award. Share-based compensation expense for restricted shares is calculated based on the grant date market price of the shares and is recognized over the vesting period.

Our share-based compensation expense is as follows:

	Year ended December 31,		
	2014	2013	2012
Cost of revenue	\$ 330	\$ 5	\$ 2
Research and development	87	1	4
Sales and marketing	949	26	18
General and administrative	1,155	108	55
Total share-based compensation expense	<u>\$ 2,521</u>	<u>\$ 140</u>	<u>\$ 79</u>

We use the Black-Scholes option pricing model to value the share option awards. The Black-Scholes option pricing model requires the input of subjective assumptions, including assumptions about the expected life of share-based payment awards and share price volatility. In addition, when we were a private company, one of the most subjective inputs into the Black-Scholes option pricing model was the estimated fair value of our ordinary shares. Due to the lack of an adequate history of a public market for the trading of our ordinary shares and a lack of adequate company specific historical and implied volatility data, we have based our estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. For these analyses, we have selected companies with comparable characteristics to ours including enterprise value, risk profiles, position within the industry, and with historical share price information sufficient to meet the expected life of the share-based awards. We compute the historical volatility data using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of our share-based awards. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own share price becomes available.

We determine the expected term for share option grants to employees based on the "simplified" method prescribed under Staff Accounting Bulletin Topic 14: Share-based Payments. Under this approach, the weighted-average expected life is presumed to be the average of the vesting term and the contractual term of the option. The risk-free interest rate is a weighted-average assumption equivalent to the expected term based on the United States Treasury yield curve in effect as of the date of grant. The assumptions used in calculating the fair value of the share-based payment awards represent our best estimate and involve inherent uncertainties and the application of our judgment. As a result, if factors change and we use different assumptions, share-based compensation expense could be materially different in the future.

For the years ended December 31, 2014, 2013, and 2012, we calculated the fair value of share options granted under the Plan using the Black-Scholes option pricing model with the following assumptions:

	Year ended December 31,		
	2014	2013	2012
Expected dividend yield (%)	—	—	—
Expected volatility (%)	46.87	47.78	49.43
Risk-free interest rate (%)	1.86	1.38	1.03
Expected life of option (years)	6.19	6.22	6.25

[Table Of Contents](#)

In accordance with Financial Accounting Standards Board, Accounting Standards Codification 718, *Compensation—Stock Compensation*, we recognize expense based on the share option grant's pre-defined vesting schedule over the requisite service period using the straight-line method for all employee share options. In addition to the assumptions used to calculate the fair value of the share options, we are required to estimate the expected forfeiture rate of all share-based awards and only recognize expense for those awards expected to vest. The estimation of the number of share awards that will ultimately vest requires judgment, and to the extent actual results or updated estimates differ from our current estimates, such amounts will be recorded as a cumulative adjustment in the period in which estimates are revised. We consider multiple factors when estimating expected forfeitures, including employee position and historical employee turnover data. During the period in which the share options vest, we will record additional expense if the actual forfeiture rate is lower than the estimated forfeiture rate and a recovery of expense if the actual forfeiture rate is higher than estimated.

Business Combinations

For acquisitions meeting the definition of a business combination, we allocate the purchase price, including any contingent consideration, to the assets acquired and the liabilities assumed at their estimated fair values as of the date of the acquisition with any excess of the purchase price paid over the estimated fair value of net assets acquired recorded as goodwill. The fair value of the assets acquired and liabilities assumed is typically determined by using either estimates of replacement costs or discounted cash flow valuation methods.

When determining the fair value of tangible assets acquired, we estimate the cost using the most appropriate valuation method with assistance from independent third party specialists. When determining the fair value of intangible assets acquired, we use judgment to estimate the applicable discount rate, growth rates and the timing and amount of future cash flows. The fair value of assets acquired and liabilities assumed is typically determined by management using the assistance of independent third party specialists. The assumptions used in calculating the fair value of tangible and intangible assets represent our best estimates. If factors change and we were to use different assumptions, valuations of tangible and intangible assets and the resulting goodwill balance related to the business combination could be materially different.

The terms of the purchase agreement with Boulder included contingent purchase price consideration consisting of future potential milestone payments totaling up to \$6.1 million at any time on or prior to July 31, 2024. The milestone payments consist of completion of studies related to acquired technologies, development of diagnostic test kits, patient enrollment in an Institutional Review Board approved study, issuance of patents, and approvals or clearances by the U.S. Food and Drug Administration. The fair value of future potential milestone payments was determined based upon a probability weighted analysis of expected future milestone payments to be made to the seller. This analysis includes significant management judgments related to the probabilities of success assigned to the milestones and to the discount rate utilized in the calculations.

Goodwill and Indefinite-lived Intangible Assets

Goodwill

Goodwill is not amortized but is reviewed for impairment at least annually, or when events or changes in the business environment indicate that all, or a portion, of the carrying value of the reporting unit may no longer be recoverable, using the two-step impairment review. Under this method, we compare the fair value of the goodwill to its carrying value. If the fair value is less than the carrying amount, a more detailed analysis is performed to determine if goodwill is impaired. An impairment loss, if any, is measured as the excess of the carrying value of goodwill over the fair value of goodwill. We also have the option to first assess qualitative factors to determine whether the existence of events or circumstances leads us to determine that it is more likely than not (that is, a likelihood of more than 50%) that goodwill is impaired. If we choose to first assess qualitative factors and it is determined that it is not more likely than not goodwill is impaired, we are not required to take further action to test for impairment. We also have the option to bypass the qualitative assessment and perform only the quantitative impairment test, which we may choose to do in some periods but not in others.

Indefinite-lived Intangible Assets

Our indefinite-lived intangible assets consist of acquired in-process research and development, or IPR&D, related to our business combination with Boulder, which were recorded at fair value on the acquisition date. IPR&D intangible assets are considered indefinite-lived intangible assets until completion or abandonment of the associated research and development efforts. IPR&D is not amortized but is reviewed for impairment at least annually, or when events or changes in the business environment indicate the carrying value may be impaired. If the fair value of the intangible asset is less than the carrying amount, we perform a quantitative test to determine the fair value. The impairment loss, if any, is measured as the excess of the carrying value of the intangible asset over its fair value. We also have the option to first assess qualitative factors to determine whether the existence of events or circumstances leads us to determine that it is more likely than not (that is, a likelihood of more than 50%) that our indefinite-lived intangible asset is impaired. If we choose to first assess qualitative factors and it is determined that it is not more likely than not our indefinite-lived intangible asset is impaired, we are not required to take further action to test for impairment. We also have the option to bypass the qualitative assessment and perform only the quantitative impairment test, which we may choose to do in some periods but not in others. The determinations as to whether, and, if so, the extent to which, acquired IPR&D become impaired are highly judgmental and based on significant assumptions regarding the projected future financial condition and operating results, changes in the manner of the use and development of the acquired assets, our overall business strategy, and regulatory, market and economic environment and trends.

[Table Of Contents](#)

On the date of the Boulder acquisition the fair value of IPR&D acquired was determined to be \$2.6 million (\$1.8 million for the Lyme disease assay, \$0.5 million for the assay to help select biologics for autoimmune disease based on monitoring and prognosis of drug response that was acquired in conjunction with the Boulder acquisition, and \$0.3 million for the gout assay) using the excess earnings method with significant inputs, including estimates of the timing and cost required for product approval, revenue growth, gross margin, operating expenses and a 15% discount rate.

Off-balance sheet arrangements

We do not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or for any other contractually narrow or limited purpose.

Recent accounting pronouncements

In May 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2014-09, *Revenue from Contracts with Customers*, or ASU 2014-09, which converges the FASB and the International Accounting Standards Board standard on revenue recognition. Under ASU 2014-09, a company should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. This guidance will be effective for us for annual and interim periods beginning after December 15, 2016. Early adoption is not permitted. The guidance allows for either “full retrospective” adoption, meaning the standard is applied to all of the periods presented, or “modified retrospective” adoption, meaning the standard is applied only to the most current period presented in the financial statements. We are currently evaluating ASU 2014-09 and have not yet determined how it may impact our financial position or results of operations and related disclosures.

In August 2014, the FASB issued ASU 2014-15, *Presentation of Financial Statements - Going Concern*, or ASU 2014-15. ASU 2014-15 will be effective for fiscal years and interim periods beginning after December 15, 2016 and early application is permitted. ASU 2014-15 requires that management evaluate at each annual and interim reporting period whether there is a substantial doubt about an entity’s ability to continue as a going concern within one year of the date that the financial statements are issued. We do not expect that the application of ASU 2014-15 will have an impact on the presentation of our results of operations, financial position or disclosures.

In November 2014, the FASB issued ASU 2014-16, *Derivatives and Hedging*, or ASU 2014-16. The objective of ASU 2014-16 is to eliminate the existing diversity in practice in accounting for hybrid financial instruments issued in the form of a share. A hybrid financial instrument consists of a “host contract” into which one or more derivative terms have been embedded. ASU 2014-16 requires an entity to consider the terms and features of the entire financial instrument, including the embedded derivative features, in order to determine whether the nature of the host contract is more akin to debt or to equity. ASU 2014-16 is effective for fiscal years and interim periods beginning after December 15, 2015, with early adoption permitted. A reporting entity should apply ASU 2014-16 using a modified retrospective approach by recording a cumulative-effect adjustment to equity as of the beginning of the annual period of adoption. Retrospective application is permitted to all relevant prior periods. We do not expect that the application of ASU 2014-16 will have an impact on the presentation of our results of operations, financial position or disclosures.

In November 2014, the FASB issued ASU 2014-17, *Business Combinations*, or ASU 2014-17. ASU 2014-17 provides guidance that allows all acquired entities to choose to apply pushdown accounting in their separate financial statements when an acquirer obtains control of them. The new guidance is effective immediately. We do not expect that the application of ASU 2014-17 will have an impact on the presentation of our results of operations, financial position or disclosures.

In January 2015, the FASB issued ASU 2015-01, *Income Statement—Extraordinary and Unusual Items*, or ASU 2015-01. ASU 2015-01 eliminates from GAAP the concept of extraordinary items. However, the presentation and disclosure guidance for items that are unusual in nature or occur infrequently will be retained and will be expanded to include items that are both unusual in nature and infrequently occurring. The amendments in ASU 2015-01 are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015. A reporting entity may apply the amendments prospectively. A reporting entity also may apply the amendments retrospectively to all prior periods presented in the financial statements. Early adoption is permitted provided that the guidance is applied from the beginning of the fiscal year of adoption. We do not expect that the application of ASU 2015-01 will have an impact on the presentation of its results of operations, financial position or disclosures.

Under the U.S. Jumpstart our Business Startups Act, or the JOBS Act, emerging growth companies that become public can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we are subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

As of December 31, 2014, we had cash and cash equivalents of \$50.2 million, and restricted cash of \$392,000. Restricted cash primarily consists of amounts pledged as security for our facility leases in the United States.

We are exposed to market risks in the ordinary course of our business. These market risks are principally limited to interest rate fluctuations, capital market fluctuations, and foreign currency exchange rate fluctuations, as discussed below.

Interest rate fluctuations

Changes in the general level of U.S. and European interest rates expose the Company to interest rate risk. These changes could affect our interest income and interest expense. Based on our cash and cash equivalents at December 31, 2014, if interest rates went either up or down one percentage point, this could change our interest income by approximately \$0.5 million per annum.

Capital market fluctuations

Our cash and cash equivalents are invested in interest-bearing savings and money market accounts. We do not enter into investments for trading or speculative purposes. We do not believe capital market fluctuations would have a material effect on the fair market value of our portfolio.

Foreign currency exchange rate fluctuations

We are exposed to foreign exchange rate risk. Because we currently operate in three major regions of the world: the United States, Europe & ROW, and Asia, our revenue is denominated in multiple currencies. About 45% of our sales are in the United States, which are denominated in U.S. Dollars. Sales in China are denominated in U.S. Dollars but these sales are made by our United Kingdom-based subsidiary where the Pound Sterling is the functional currency. As a result, these sales are subject to remeasurement into Pounds Sterling and then translation into U.S. Dollars when we consolidate our financial statements. Sales in Europe are denominated primarily in the Pound Sterling and Euro. As we grow Europe & ROW sales outside the United Kingdom and the Euro Zone, we will be subject to risk from additional currencies. Sales in Japan are denominated in Yen, and our sales in Japan, which started in late 2012, grew significantly in 2013.

Our expenses are generally denominated in the currencies in which our operations are located, which is primarily in the United States, the United Kingdom and Japan.

As we continue to grow our business outside the United States, our results of operations and cash flows will be subject to fluctuations due to changes in foreign currency exchange rates, which could harm our business in the future. To date, we have not entered into any foreign currency hedging contracts although we may do so in the future.

Item 8. Financial Statements and Supplementary Data

The information required by this item may be found beginning on page F-1 of this Annual Report on Form 10-K with the exception of the unaudited consolidated quarterly operations data, which is presented below. We have prepared the consolidated quarterly operations data on a consistent basis with the audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K. In the opinion of management, the quarterly consolidated operations data reflects all necessary adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of these data. Historical results are not necessarily indicative of the results to be expected in future periods, and the results for a quarterly period are not necessarily indicative of the operating results for a full year. This information should be read in conjunction with the consolidated financial statements included elsewhere in this Annual Report Form 10-K.

(in thousands, except share and per share data) (unaudited)	Three months ended			
	March 31, 2014	June 30, 2014	September 30, 2014	December 31, 2014 (1)
Revenue:				
Product	\$ 6,825	\$ 5,887	\$ 6,480	\$ 6,215
Service	5,449	5,901	6,845	5,903
Total revenue	\$ 12,274	\$ 11,788	\$ 13,325	\$ 12,118
Gross profit	\$ 6,262	\$ 5,795	\$ 6,813	\$ 6,626
Net loss	\$ (3,153)	\$ (6,234)	\$ (6,095)	\$ (6,692)
Net loss per share attributable to ordinary shareholders—basic and diluted	\$ (0.18)	\$ (0.36)	\$ (0.35)	\$ (0.39)
Weighted-average shares used to compute net loss attributable to ordinary shareholders—basic and diluted	17,264,135	17,292,251	17,333,441	17,337,646

(in thousands, except share and per share data) (unaudited)	Three months ended			
	March 31, 2013	June 30, 2013	September 30, 2013 (2)	December 31, 2013 (2)
Revenue:				
Product	\$ 4,121	\$ 5,790	\$ 4,977	\$ 5,017
Service	3,558	4,364	5,749	5,208
Total revenue	\$ 7,679	\$ 10,154	\$ 10,726	\$ 10,225
Gross profit	\$ 3,312	\$ 5,287	\$ 5,795	\$ 5,790
Net loss	\$ (1,201)	\$ (954)	\$ (3,181)	\$ (3,328)
Net loss per share attributable to ordinary shareholders—basic and diluted	\$ (0.56)	\$ (0.42)	\$ (1.36)	\$ (0.38)
Weighted-average shares used to compute net loss attributable to ordinary shareholders—basic and diluted	2,154,285	2,253,788	2,331,990	8,721,880

- (1) Net loss includes \$182,000 of restructuring charges related to the closing of facilities that had been used by Boulder and consolidating the research and development activities that had been performed at those locations to the Company's Memphis, Tennessee and Abingdon, U.K. facilities.
- (2) Net loss includes \$1.2 million and \$0.6 million of accounting and auditing costs related to our Initial Public Offering (IPO) for the three months ended September 30, 2013 and December 31, 2013, respectively.

Our revenue fluctuates from quarter to quarter as a result of a number of factors, many of which are outside our control. Our service revenue has historically been strong in the third quarter as a result of a concentration of testing in the United States related to college students returning to school, while the fourth quarter has historically been weaker due to the holiday periods and decreased screening activity in hospitals as they focus on other priorities. Additionally, we see fluctuation in our product revenue from quarter to quarter, due to ordering patterns, particularly relating to our large distributor customers. As a result of such factors, we expect to continue to see seasonality and quarter-to-quarter variations in our revenue.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

There have been no changes in or disagreements with accountants on accounting and financial disclosure matters in the last fiscal year.

Item 9A. Controls and procedures

(a) Evaluation of disclosure controls and procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this Form 10-K. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and is accumulated and communicated to our management, including our Chief Executive and Chief Financial Officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

(b) Management's report on internal control over financial reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Securities Exchange Act Rule 13a-15(f). Under the supervision and with the participation of our management, including our Chief Executive Officer and Principal Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control—Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2014.

(c) Changes in internal control over financial reporting

There have been no changes to our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fourth quarter of 2014 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, to be filed with the Commission not later than 120 days after the close of our fiscal year ended December 31, 2014.

Item 11. Executive Compensation

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, to be filed with the Commission not later than 120 days after the close of our fiscal year ended December 31, 2014.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, to be filed with the Commission not later than 120 days after the close of our fiscal year ended December 31, 2014.

Item 13. Certain Relationships and Related Transactions and Director Independence

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, to be filed with the Commission not later than 120 days after the close of our fiscal year ended December 31, 2014.

Item 14. Principal Accounting Fees and Services

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, to be filed with the Commission not later than 120 days after the close of our fiscal year ended December 31, 2014.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a) 1. Financial Statements

As part of this Annual Report on Form 10-K, the consolidated financial statements are listed in the accompanying index to financial statements on page F-1.

2. Financial Statement Schedules

All schedules have been omitted because they are not required, not applicable, not present in amounts sufficient to require submission of the schedule, or the required information is otherwise included.

3. Exhibit Index

The following is a list of exhibits filed as part of this Annual Report on Form 10-K:

Exhibit number	Description of exhibit
3.1	Articles of Association of the Registrant (Filed as Exhibit 3.1 of our Form 8-K on June 18, 2014 and incorporated herein by reference.)
4.1	Form of Ordinary Shares Certificate (Filed as Exhibit 3.2 of Amendment No. 5 to our Registration Statement on Form S-1 (File No. 333-191737) on November 8, 2013 and incorporated herein by reference.)
4.2	Registration Rights Agreement (Filed as Exhibit 4.2 of our Form 10-K on March 27, 2014 and incorporated herein by reference.)
4.3	Warrant to Purchase Ordinary Shares, issued to Comerica Bank (Filed as Exhibit 4.3 of our Form 10-K on March 27, 2014 and incorporated herein by reference.)
4.4	Warrant to Purchase Ordinary Shares, issued to Square 1 Bank (Filed as Exhibit 4.4 of our Form 10-K on March 27, 2014 and incorporated herein by reference.)
10.1+	License Agreement dated July 27, 2005 between Isis Innovation Limited and Oxford Immunotec Limited (Filed as Exhibit 10.1 of our Registration Statement on Form S-1 (File No. 333-191737) on October 15, 2013 and incorporated herein by reference.)
10.2+	2006 Deed of Variation to License Agreement between Isis Innovation Limited and Oxford Immunotec Limited (Filed as Exhibit 10.2 of our Registration Statement on Form S-1 (File No. 333-191737) on October 15, 2013 and incorporated herein by reference.)
10.3+	Letter Agreement Amendment dated December 13, 2012 to License Agreement between Isis Innovation Limited and Oxford Immunotec Limited (Filed as Exhibit 10.3 of our Registration Statement on Form S-1 (File No. 333-191737) on October 15, 2013 and incorporated herein by reference.)
10.4+	Assignment dated November 20, 2013 between Isis Innovation Limited and Oxford Immunotec Limited (Filed as Exhibit 10.4 of our Form 10-K on March 27, 2014 and incorporated herein by reference.)
10.5+	License and Supply Agreement dated December 22, 2009 between Statens Serum Institut and Oxford Immunotec Limited (Filed as Exhibit 10.4 of Amendment No. 1 of our Registration Statement on Form S-1 (File No. 333-191737) on October 25, 2013 and incorporated herein by reference.)
10.6	Supplement dated November 9, 2010 to License and Supply Agreement between Statens Serum Institut and Oxford Immunotec Limited (Filed as Exhibit 10.5 of Amendment No. 1 of our Registration Statement on Form S-1 (File No. 333-191737) on October 25, 2013 and incorporated herein by reference.)
10.7+	License Agreement dated June 30, 2006 between Rutgers, The State University of New Jersey and Oxford Immunotec Limited (Filed as Exhibit 10.6 of our Registration Statement on Form S-1 (File No. 333-191737) on October 15, 2013 and incorporated herein by reference.)

Exhibit number	Description of exhibit
10.8+	First Amendment dated July 1, 2009 to License Agreement between Rutgers, The State University of New Jersey and Oxford Immunotec Limited (Filed as Exhibit 10.7 of our Registration Statement on Form S-1 (File No. 333-191737) on October 15, 2013 and incorporated herein by reference.)
10.9+	Second Amendment dated January 6, 2011 to License Agreement between Rutgers, The State University of New Jersey and Oxford Immunotec Limited (Filed as Exhibit 10.8 of our Registration Statement on Form S-1 (File No. 333-191737) on October 15, 2013 and incorporated herein by reference.)
10.10	Third Amendment dated December 20, 2012 to License Agreement between Rutgers, The State University of New Jersey and Oxford Immunotec Limited (Filed as Exhibit 10.9 of our Registration Statement on Form S-1 (File No. 333-191737) on October 15, 2013 and incorporated herein by reference.)
10.11+	Fourth Amendment dated April 24, 2013 to License Agreement between Rutgers, The State University of New Jersey and Oxford Immunotec Limited (Filed as Exhibit 10.10 of our Registration Statement on Form S-1 (File No. 333-191737) on October 15, 2013 and incorporated herein by reference.)
10.12+	Supply Agreement dated December 17, 2010 between MicroCoat Biotechnologie GmbH and Oxford Immunotec Limited (Filed as Exhibit 10.11 of our Registration Statement on Form S-1 (File No. 333-191737) on October 15, 2013 and incorporated herein by reference.)
10.13+	Purchase Agreement dated February 6, 2010 between Mabtech AB and Oxford Immunotec Limited (Filed as Exhibit 10.12 of our Registration Statement on Form S-1 (File No. 333-191737) on October 15, 2013 and incorporated herein by reference.)
10.14+	Amendment to Purchase Agreement dated September 10, 2013 between Mabtech AB and Oxford Immunotec Limited (Filed as Exhibit 10.13 of our Registration Statement on Form S-1 (File No. 333-191737) on October 15, 2013 and incorporated herein by reference.)
10.15+	Manufacturing Agreement dated August 26, 2003 between Mabtech AB and Oxford Immunotec Limited (Filed as Exhibit 10.14 of our Registration Statement on Form S-1 (File No. 333-191737) on October 15, 2013 and incorporated herein by reference.)
10.16	First Amendment dated January 1, 2010 to Manufacturing Agreement between Mabtech AB and Oxford Immunotec Limited (Filed as Exhibit 10.15 of our Registration Statement on Form S-1 (File No. 333-191737) on October 15, 2013 and incorporated herein by reference.)
10.17	Second Amendment dated May 24, 2011 to Manufacturing Agreement between Mabtech AB and Oxford Immunotec Limited (Filed as Exhibit 10.16 of our Registration Statement on Form S-1 (File No. 333-191737) on October 15, 2013 and incorporated herein by reference.)
10.18+	Supply Agreement dated January 1, 2009 between EMD Millipore Corporation and Oxford Immunotec Ltd (Filed as Exhibit 10.17 of our Registration Statement on Form S-1 (File No. 333-191737) on October 15, 2013 and incorporated herein by reference.)
10.19+	First Amendment to Supply Agreement dated September 27, 2013 between EMD Millipore Corporation and Oxford Immunotec Limited (Filed as Exhibit 10.18 of our Registration Statement on Form S-1 (File No. 333-191737) on October 15, 2013 and incorporated herein by reference.)
10.20+	Second Amendment to Supply Agreement dated March 25, 2014 between EMD Millipore Corporation and Oxford Immunotec Limited (Filed as Exhibit 10.20 of our Form 10-K on March 27, 2014 and incorporated herein by reference.)
10.21+	Supply Agreement dated January 31, 2008 between StemCell Technologies, Inc. and Oxford Immunotec Limited (Filed as Exhibit 10.19 of our Registration Statement on Form S-1 (File No. 333-191737) on October 15, 2013 and incorporated herein by reference.)

Exhibit number	Description of exhibit
10.22 ⁺	Amendment dated October 26, 2011 to Supply Agreement between StemCell Technologies, Inc. and Oxford Immunotec Limited (Filed as Exhibit 10.20 of our Registration Statement on Form S-1 (File No. 333-191737) on October 15, 2013 and incorporated herein by reference.)
10.23 ⁺	Supply and Reseller Agreement dated August 12, 2013 between Life Technologies Corporation and Oxford Immunotec Limited (Filed as Exhibit 10.21 of our Registration Statement on Form S-1 (File No. 333-191737) on October 15, 2013 and incorporated herein by reference.)
10.24 ⁺	First Amendment to Supply and Reseller Agreement ,dated April 1, 2014 between Life Technologies Corporation and Oxford Immunotec Limited (Filed as Exhibit 10. 1 of our Form 8-K on April 3, 2014 and incorporated herein by reference.)
10.25 ⁺	Distributorship Agreement dated October 8, 2013 among Shanghai Fosun Long March Medical Science Co. Ltd., Shanghai Xin Chang Medical Device Co. Ltd. and Oxford Immunotec Limited (Filed as Exhibit 10.24 of our Registration Statement on Form S-1 (File No. 333-191737) on October 15, 2013 and incorporated herein by reference.)
10.26 ⁺	Marketing Authorization Holder Agreement dated July 29, 2011 between Riken Genesis Co., Ltd. and Oxford Immunotec Limited (Filed as Exhibit 10.25 of our Registration Statement on Form S-1 (File No. 333-191737) on October 15, 2013 and incorporated herein by reference.)
10.27 ⁺	Amendment to Marketing Authorization Holder Agreement dated September 1, 2013 between Riken Genesis Co., Ltd. and Oxford Immunotec Limited (Filed as Exhibit 10.26 of our Registration Statement on Form S-1 (File No. 333-191737) on October 15, 2013 and incorporated herein by reference.)
10.28	Amended and Restated 2008 Stock Incentive Plan (Filed as Exhibit 10.35 of our Registration Statement on Form S-1 (File No. 333-191737) on October 15, 2013 and incorporated herein by reference.)
10.29	Form of Incentive Stock Option Award for executive officers under the Amended and Restated 2008 Stock Incentive Plan (Filed as Exhibit 10.36 of our Registration Statement on Form S-1 (File No. 333-191737) on October 15, 2013 and incorporated herein by reference.)
10.30	Form of Non-Statutory Stock Option Award for Non-Executive Directors under the Amended and Restated 2008 Stock Incentive Plan (Filed as Exhibit 10.37 of our Registration Statement on Form S-1 (File No. 333-191737) on October 15, 2013 and incorporated herein by reference.)
10.31	Form of Enterprise Management Incentive Stock Option Agreement for Chief Executive Officer under the Amended and Restated 2008 Stock Incentive Plan (Filed as Exhibit 10.38 of our Registration Statement on Form S-1 (File No. 333-191737) on October 15, 2013 and incorporated herein by reference.)
10.32	Oxford Immunotec Global PLC 2013 Share Incentive Plan (Filed as Exhibit 10.39 of Amendment No. 6 of our Registration Statement on Form S-1 (File No. 333-191737) on November 14, 2013 and incorporated herein by reference.)
10.33	Oxford Immunotec Global PLC Incentive Plan (Filed as Exhibit 10.40 of Amendment No. 2 to our Registration Statement on Form S-1 (File No. 333-191737) on November 4, 2013 and incorporated herein by reference.)
10.34	Form of Restricted Share Award Certificate under the Oxford Immunotec Global PLC 2013 Share Incentive Plan for officers resident in the United Kingdom (Filed as Exhibit 10.1 of our Form 8-K on March 6, 2014 and incorporated herein by reference.)
10.35	Form of Restricted Share Award Certificate under the Oxford Immunotec Global PLC 2013 Share Incentive Plan for officers resident in the United States (Filed as Exhibit 10.2 of our Form 8-K on March 6, 2014 and incorporated herein by reference.)

Exhibit number	Description of exhibit
10.36	Form of CSOP award certificate under the Oxford Immunotec Global PLC 2013 Share Incentive Plan for officers resident in the United Kingdom (Filed as Exhibit 10.3 of our Form 8-K on March 6, 2014 and incorporated herein by reference.)
10.37	Form of unapproved option under the Oxford Immunotec Global PLC 2013 Share Incentive Plan for officers resident in the United Kingdom (Filed as Exhibit 10.4 of our Form 8-K on March 6, 2014 and incorporated herein by reference.)
10.38	Form of stock option agreement under the Oxford Immunotec Global PLC 2013 Share Incentive Plan for officers resident in the United States (Filed as Exhibit 10.5 of our Form 8-K on March 6, 2014 and incorporated herein by reference.)
10.39	Service Agreement dated October 21, 2002 between Oxford Immunotec Limited and Peter Wrighton-Smith, as amended through 2013 (Filed as Exhibit 10.45 of our Form 10-K on March 27, 2014 and incorporated herein by reference.)
10.40	Amended and Restated Employment Agreement dated October 1, 2013 between Oxford Immunotec, Inc. and Jeff R. Schroeder (Filed as Exhibit 10.42 of our Registration Statement on Form S-1 (File No. 333-191737) on October 15, 2013 and incorporated herein by reference.)
10.41	Amended and Restated Employment Agreement dated October 1, 2013 between Oxford Immunotec, Inc. and Richard M. Altieri (Filed as Exhibit 10.43 of our Registration Statement on Form S-1 (File No. 333-191737) on October 15, 2013 and incorporated herein by reference.)
10.42	Form of Deed of Indemnity for Directors (Filed as Exhibit 10.44 of Amendment No. 5 to our Registration Statement on Form S-1 (File No. 333-191737) on November 8, 2013 and incorporated herein by reference.)
10.43	Form of Deed of Indemnity for Officers (Filed as Exhibit 10.45 of Amendment No. 5 to our Registration Statement on Form S-1 (File No. 333-191737) on November 8, 2013 and incorporated herein by reference.)
10.44	Form of Non-Executive Director Appointment Letter (Filed as Exhibit 10.46 of Amendment No. 2 to our Registration Statement on Form S-1 (File No. 333-191737) on November 4, 2013 and incorporated herein by reference.)
10.45	Oxford Immunotec Global PLC Management Incentive Compensation Plan for Fiscal Years 2012 and 2013 (Filed as Exhibit 10.47 of Amendment No. 2 to our Registration Statement on Form S-1 (File No. 333-191737) on November 4, 2013 and incorporated herein by reference.)
10.46	Form of Director Stock Option Award under Oxford Immunotec Global PLC Share Incentive Plan (Filed as Exhibit 10.48 of Amendment No. 5 to our Registration Statement on Form S-1 (File No. 333-191737) on November 8, 2013 and incorporated herein by reference.)
10.47	Deed of Novation of Agreement for Services dated November 8, 2013 by and among Oxford Immunotec Limited, Oxford Immunotec Global PLC and Peter Wrighton-Smith (Filed as Exhibit 10.49 of Amendment No. 5 to our Registration Statement on Form S-1 (File No. 333-191737) on November 8, 2013 and incorporated herein by reference.)
10.48	Form of First Amendment to Officer Restricted Share Award under Appendix C of the 2013 Share Incentive Plan (Filed as Exhibit 10.1 of our Form 8-K on January 2, 2015 and incorporated herein by reference.)
10.49	Form of First Amendment to Officer Stock Option Award under Appendix D of the 2013 Share Incentive Plan (Filed as Exhibit 10.2 of our Form 8-K on January 2, 2015 and incorporated herein by reference.)
21.1	List of Subsidiaries
23.1	Consent of Ernst & Young LLP

[Table Of Contents](#)

Exhibit number	Description of exhibit
24.1	Power of Attorney executed by Directors and Officers (included on signature page)
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101	The following materials from the Company's Annual Report on Form 10-K for the year ended December 31, 2014, formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated balance sheets as of December 31, 2014 and 2013; (ii) Consolidated statements of operations for the years ended December 31, 2014, 2013 and 2012; (iii) Consolidated statements of other comprehensive loss for the years ended December 31, 2014, 2013 and 2012; (iv) Consolidated statements of shareholders' equity for the years ended December 31, 2014, 2013 and 2012; (v) Consolidated statements of cash flows for the years ended December 31, 2014, 2013 and 2012; and (vi) Notes to consolidated financial statements.

+ Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been submitted separately to the Securities and Exchange Commission.

Signatures

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in Abingdon, England, on March 5, 2015.

OXFORD IMMUNOTEC GLOBAL PLC

By: /s/ Peter Wrighton-Smith, Ph.D.
Peter Wrighton-Smith, Ph.D.
Chief Executive Officer and Director

Power of Attorney

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Peter Wrighton-Smith, Ph.D., Richard M. Altieri, and Elizabeth M. Keiley, and each of them, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming that all said attorneys-in-fact and agents, or any of them or their or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant on March 5, 2015 in the capacities indicated below.

Signature	Title	Date
<u>/s/ Peter Wrighton-Smith, Ph.D.</u> Peter Wrighton-Smith, Ph.D.	Chief Executive Officer and Director (Principal Executive Officer)	March 5, 2015
<u>/s/ Richard M. Altieri</u> Richard M. Altieri	Chief Financial Officer (Principal Financial and Accounting Officer)	March 5, 2015
<u>/s/ Richard A. Sandberg</u> Richard A. Sandberg	Chairman of the Board of Directors	March 5, 2015
<u>/s/ Stephen L. Spotts</u> Stephen L. Spotts	Director	March 5, 2015
<u>/s/ Nigel A. Pitchford, Ph.D.</u> Nigel A. Pitchford, Ph.D.	Director	March 5, 2015
<u>/s/ Patricia Randall</u> Patricia Randall	Director	March 5, 2015
<u>/s/ Herm Rosenman</u> Herm Rosenman	Director	March 5, 2015
<u>/s/ James R. Tobin</u> James R. Tobin	Director	March 5, 2015
<u>/s/ Richard M. Altieri</u> Richard M. Altieri	Authorized Representative in the United States	March 5, 2015

Oxford Immunotec Global PLC

Index to financial statements

Audited consolidated financial statements

	<u>Page</u>
Report of independent registered public accounting firm	F-2
Consolidated balance sheets as of December 31, 2014 and 2013	F-3
Consolidated statements of operations for the years ended December 31, 2014, 2013 and 2012	F-4
Consolidated statements of other comprehensive loss for the years ended December 31, 2014, 2013 and 2012	F-5
Consolidated statements of shareholders' equity for the years ended December 31, 2014, 2013 and 2012	F-6
Consolidated statements of cash flows for the years ended December 31, 2014, 2013 and 2012	F-8
Notes to the consolidated financial statements	F-10

Report of independent registered public accounting firm

The Board of Directors and Shareholders of Oxford Immunotec Global PLC:

We have audited the accompanying consolidated balance sheets of Oxford Immunotec Global PLC as of December 31, 2014 and 2013, and the related consolidated statements of operations, other comprehensive loss, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2014. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Oxford Immunotec Global PLC at December 31, 2014 and 2013, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2014, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Reading, United Kingdom

March 5, 2015

Oxford Immunotec Global PLC
Consolidated balance sheets
(in thousands, except share and per share data)

	December 31,	
	2014	2013
Assets		
Current assets:		
Cash and cash equivalents	\$ 50,165	\$ 76,494
Restricted cash	200	87
Accounts receivable, net	6,823	4,754
Inventory	6,425	5,450
Prepaid expenses and other	2,755	2,242
Total current assets	66,368	89,027
Restricted cash, non-current	192	362
Property and equipment, net	4,537	2,964
In-process research and development	2,399	—
Goodwill	50	—
Other intangible assets, net	273	331
Other assets	30	60
Total assets	<u>\$ 73,849</u>	<u>\$ 92,744</u>
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	\$ 2,368	\$ 2,310
Accrued liabilities	7,070	6,936
Deferred income	1,993	1,540
Current portion of loans payable	137	170
Taxes payable	—	177
Total current liabilities	11,568	11,133
Long-term portion of loans payable	454	563
Contingent purchase price consideration	1,218	—
Other liabilities	—	296
Total liabilities	13,240	11,992
Commitments and contingencies (Note 16)		
Shareholders' equity:		
Ordinary shares, £0.006705 nominal value; 40,103,528 and 25,189,285 shares authorized at December 31, 2014 and 2013, respectively, 17,614,650 and 17,255,267, shares issued and outstanding at December 31, 2014 and 2013, respectively.	192	188
Additional paid-in capital	186,816	183,967
Accumulated deficit	(121,829)	(99,655)
Accumulated other comprehensive loss	(4,570)	(3,748)
Total shareholders' equity	60,609	80,752
Total liabilities and shareholders' equity	<u>\$ 73,849</u>	<u>\$ 92,744</u>

See accompanying notes to these consolidated financial statements.

Oxford Immunotec Global PLC
Consolidated statements of operations
(in thousands, except share and per share data)

	Year ended December 31,		
	2014	2013	2012
Revenue			
Product	\$ 25,407	\$ 19,905	\$ 9,080
Service	24,098	18,879	11,605
Total revenue	49,505	38,784	20,685
Cost of revenue			
Product	11,225	8,475	4,329
Service	12,784	10,125	8,095
Total cost of revenue	24,009	18,600	12,424
Gross profit	25,496	20,184	8,261
Operating expenses:			
Research and development	7,033	2,146	1,947
Sales and marketing	25,487	13,270	11,177
General and administrative	14,837	12,119	8,068
Total operating expenses	47,357	27,535	21,192
Loss from operations	(21,861)	(7,351)	(12,931)
Other income (expense):			
Interest expense, net	(52)	(328)	(1,477)
Foreign exchange losses	(352)	(423)	(626)
Other income (expense)	245	(470)	—
Loss before income taxes	(22,020)	(8,572)	(15,034)
Income tax expense (benefit)	154	92	(151)
Net loss	\$ (22,174)	\$ (8,664)	\$ (14,883)
Net loss per share attributable to ordinary shareholders—basic and diluted	\$ (1.28)	\$ (2.26)	\$ (8.44)
Weighted-average shares used to compute net loss attributable to ordinary shareholders—basic and diluted	17,310,148	3,830,837	1,763,728

See accompanying notes to these consolidated financial statements.

Oxford Immunotec Global PLC
Consolidated statements of other comprehensive loss
(in thousands)

	Year ended December 31,		
	2014	2013	2012
Net loss	\$ (22,174)	\$ (8,664)	\$ (14,883)
Other comprehensive (loss) income, net of taxes:			
Foreign currency translation adjustment, net of taxes	(822)	(126)	345
Other comprehensive (loss) income, net of taxes	(822)	(126)	345
Total comprehensive loss	<u>\$ (22,996)</u>	<u>\$ (8,790)</u>	<u>\$ (14,538)</u>

See accompanying notes to these consolidated financial statements.

Oxford Immunotec Global PLC
Consolidated statements of shareholders' equity
(in thousands)

	Convertible preferred ordinary shares						Subscription G preferred ordinary	Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive (loss) income	Total shareholders' equity	
	A preferred ordinary	B preferred ordinary	D preferred ordinary	E preferred ordinary	F preferred ordinary	G preferred ordinary						
Balance at December 31, 2011	\$ 2	\$ 1	\$ 5	\$ 33	\$ 25	\$ —	14	\$ —	85,221	\$(76,108)	\$(3,967)	5,226
Issuance of ordinary shares —anti-dilution	—	—	—	—	—	—	9	—	(9)	—	—	—
Issuance of F preferred ordinary shares in connection with debt financing	—	—	—	—	1	—	1	—	1,314	—	—	1,316
Subscription of G preferred ordinary shares	—	—	—	—	—	—	—	8,075	—	—	—	8,075
Issuance of G preferred ordinary shares, net of financing costs	—	—	—	—	—	16	—	—	16,685	—	—	16,701
Interest on convertible notes settled with G preferred ordinary shares	—	—	—	—	—	—	—	—	90	—	—	90
Share-based compensation expense	—	—	—	—	—	—	—	—	79	—	—	79
Other comprehensive income	—	—	—	—	—	—	—	—	—	—	345	345
Net loss	—	—	—	—	—	—	—	—	—	(14,883)	—	(14,883)
Balance at December 31, 2012	2	1	5	33	26	16	24	8,075	103,380	(90,991)	(3,622)	16,949
Exercise of share options	—	—	—	—	—	—	1	—	21	—	—	22
Issuance of G preferred ordinary shares, net of financing costs	—	—	—	—	—	11	—	(8,075)	11,006	—	—	2,942
Conversion of preferred ordinary shares in connection with initial public offering	(2)	(1)	(5)	(33)	(26)	(27)	94	—	—	—	—	—
Ordinary shares issued in connection with initial public offering, net of offering costs	—	—	—	—	—	—	67	—	63,812	—	—	63,879
Ordinary shares issued upon conversion of note payable and accrued interest	—	—	—	—	—	—	2	—	5,608	—	—	5,610

Share-based compensation expense	—	—	—	—	—	—	—	—	140	—	—	140
Other comprehensive loss	—	—	—	—	—	—	—	—	—	—	(126)	(126)
Net loss	—	—	—	—	—	—	—	—	—	(8,664)	—	(8,664)
Balance at December 31, 2013	—	—	—	—	—	—	188	—	183,967	(99,655)	(3,748)	80,752

Oxford Immunotec Global PLC
Consolidated statements of shareholders' equity (continued)
(in thousands)

	Convertible preferred ordinary shares							Subscription G preferred ordinary	Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive (loss) income	Total shareholders' equity
	A preferred ordinary	B preferred ordinary	D preferred ordinary	E preferred ordinary	F preferred ordinary	G preferred ordinary	Ordinary					
Exercise of share options	—	—	—	—	—	—	1	—	13	—	—	14
Issuance of shares from option plan	—	—	—	—	—	—	3	—	(3)	—	—	—
Issuance of shares from exercise of warrants	—	—	—	—	—	—	—	—	318	—	—	318
Share-based compensation expense	—	—	—	—	—	—	—	—	2,521	—	—	2,521
Other comprehensive loss	—	—	—	—	—	—	—	—	—	—	(822)	(822)
Net loss	—	—	—	—	—	—	—	—	—	(22,174)	—	(22,174)
Balance at December 31, 2014	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 192	\$ —	\$ 186,816	\$ (121,829)	\$ (4,570)	\$ 60,609

See accompanying notes to these consolidated financial statements.

Oxford Immunotec Global PLC
Consolidated statements of cash flows
(in thousands)

	Year ended December 31,		
	2014	2013	2012
Cash flows from operating activities			
Net loss	\$ (22,174)	\$ (8,664)	\$ (14,883)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,742	1,101	801
Share-based compensation expense	2,521	140	79
Loss on change in fair value of warrants	22	279	—
Loss on change in fair value of derivative instrument	—	561	—
(Gain) loss on disposal of property and equipment	—	(1)	71
Noncash interest expense	—	—	1,425
Changes in operating assets and liabilities:			
Accounts receivable, net	(2,311)	637	(3,103)
Inventory	(1,214)	(2,808)	(1,045)
Prepaid expenses and other	(594)	(881)	(333)
Accounts payable	(109)	483	196
Accrued liabilities	768	2,947	1,608
Deferred income	572	587	814
Net cash used in operating activities	(20,777)	(5,619)	(14,370)
Cash flows from investing activities			
Purchases of property and equipment	(3,014)	(1,809)	(1,482)
Purchases of intangible assets	(354)	(205)	(79)
Cash paid for acquisition, net of cash acquired	(1,716)	—	—
Proceeds on sales of property and equipment	—	22	—
Change in restricted cash	57	225	(315)
Net cash used in investing activities	(5,027)	(1,767)	(1,876)
Cash flows from financing activities			
Proceeds from revolving line of credit	—	—	1,500
Proceeds from convertible note	—	4,842	4,000
Proceeds received in advance of share issuance	—	—	8,075
Proceeds from issuance of ordinary shares	—	63,879	—
Proceeds from issuance of preferred ordinary shares	—	2,942	12,701
Proceeds from exercise of share options	14	22	1
Proceeds from term loan	—	6,582	—
Payments on loan	(165)	(6,068)	(60)
Payments on revolving line of credit	—	(1,500)	—
Net cash (used in) provided by financing activities	(151)	70,699	26,217
Effect of exchange rate changes on cash and cash equivalents	(374)	603	273
Net (decrease) increase in cash and cash equivalents, excluding restricted cash	(26,329)	63,916	10,244
Cash and cash equivalents at beginning of year	76,494	12,578	2,334
Cash and cash equivalents at end of year	\$ 50,165	\$ 76,494	\$ 12,578

See accompanying notes to these consolidated financial statements.

Oxford Immunotec Global PLC
Consolidated statements of cash flows (continued)
(in thousands)

	Year ended December 31,		
	2014	2013	2012
Supplemental disclosures			
Cash paid for interest	\$ 50	\$ 240	\$ 81
Cash paid (received) for taxes	115	70	(281)
Noncash investing and financing activities			
Interest on convertible notes settled with G preferred ordinary shares	\$ —	\$ —	\$ 90
F preferred ordinary shares issued with convertible notes	—	—	1,316
Convertible notes converted into G preferred ordinary shares	—	—	4,000
Fair value of warrant issued with convertible note	—	296	—
Conversion of note and accrued interest into ordinary shares	—	5,049	—
Warrants liability reclassified to additional paid-in capital upon exercise of warrants	318	—	—

See accompanying notes to these consolidated financial statements.

Oxford Immunotec Global PLC

Notes to consolidated financial statements

1. Description of business and significant accounting policies

Description of business

Oxford Immunotec Global PLC (the “Company”), is a global, commercial-stage diagnostics company focused on developing and commercializing proprietary tests for the management of immune-regulated conditions. The Company’s proprietary T-SPOT technology platform allows it to measure the responses of specific immune cells to inform the diagnosis, prognosis and monitoring of patients with immune-regulated conditions. Substantially all of the Company’s revenue is currently derived from the sale of its T-SPOT.TB test, which is sold in two formats: an *in vitro* diagnostic kit format (allowing customers to perform the test at their own institutions), and a service format (in which the Company performs the test on samples sent by customers to the Company’s own laboratory facilities). The Company markets its T-SPOT.TB test through a direct sales force in the United States, certain European countries, and Japan. The Company markets its test through distributors in other parts of the world.

On July 31, 2014, the Company acquired substantially all of the assets of Boulder Diagnostics, Inc. (“Boulder”), a privately owned company developing immunology-based assays for autoimmune and inflammatory conditions/diseases. The assets acquired primarily relate to assays for Lyme disease and gout and an assay to inform decisions regarding biologic therapies.

Reorganization, reverse share split and conversion, and initial public offering

On October 2, 2013, the Company completed a scheme of arrangement under the laws of England and Wales, or the Scheme of Arrangement, which was approved by the High Court of Justice in England and Wales. All holders of ordinary shares, preferred ordinary shares, options and warrants exchanged their interests in Oxford Immunotec Limited for identical interests in Oxford Immunotec Global PLC. As a result of this exchange, Oxford Immunotec Global PLC became the parent company of Oxford Immunotec Limited.

In November 2013, prior to closing of the Company’s initial public offering, the Company undertook a 1 for 6.705 reverse share split of its outstanding ordinary shares, which resulted in a proportional decrease in the number of ordinary shares outstanding as well as appropriate adjustments to outstanding A ordinary shares, preferred ordinary shares, warrants and options. After the reverse share split and immediately prior to the Company’s IPO, all outstanding preferred ordinary shares converted into ordinary shares. The nominal value of the ordinary shares was adjusted from £0.001 to £0.006705 per share. Prior period share and per share amounts have been adjusted to reflect the reverse share split.

On November 21, 2013, the registration statement for the Company’s initial public offering, or IPO, was declared effective by the Securities and Exchange Commission. The Company sold 6,164,000 ordinary shares, at an initial public offering price of \$12.00 per share, which included the exercise in full by the underwriters of their option to purchase up to 804,000 additional ordinary shares. Net proceeds from the IPO were \$63.9 million, after deducting underwriting discounts and commissions and offering expenses.

Initial public offering (IPO) costs

Incremental costs incurred that were directly attributable to the November 2013 offering of securities were deferred and deducted from the related proceeds of the offering, and the net amount recorded as contributed shareholders’ equity in the period when such shares were issued. As at December 31, 2013, the Company had deducted \$10.1 million from the related net proceeds of the offering for underwriting and other fees. Other costs incurred in the offering of \$1.9 million (which were principally related to audit and accounting expenses) in the year ended December 31, 2013, were expensed as incurred and included in general and administrative expenses.

Basis of presentation, accounting principles and principles of consolidation

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (U.S. GAAP), and include the financial statements of Oxford Immunotec Global PLC, a company incorporated in England and Wales and its wholly-owned subsidiaries, collectively referred to as the Company. The financial statements include the results of Oxford Immunotec Limited and its consolidated subsidiaries for the period prior to the completion of the Scheme of Arrangement, as well as the results of Oxford Immunotec Global PLC and its consolidated subsidiaries for the period after completion of the Scheme of Arrangement. All intercompany accounts and transactions have been eliminated upon consolidation.

Segment reporting

The Company operates in one operating segment. The Company’s chief operating decision maker (the CODM), its chief executive officer, manages the Company’s operations on an integrated basis for the purposes of allocating resources. When evaluating the Company’s financial performance, the CODM reviews separate revenue information for the Company’s product and service offerings and for each country, while all other financial information is on a combined basis. While the Company’s principal operations and decision-making functions are located in both the United States and United Kingdom, the CODM makes decisions on a global basis. Accordingly, the Company has determined that it operates in a single reporting segment.

Use of estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the consolidated financial statements and that affect the reported amounts of revenue and expenditures during the reporting periods. Actual results could differ from those estimates and assumptions used.

Foreign currency translation

The functional currency for Oxford Immunotec Global PLC is the U.S. Dollar. The functional currency for the Company's operating subsidiaries are the Pound Sterling for Oxford Immunotec Limited, the U.S. Dollar for Oxford Immunotec Inc., the Yen for Oxford Immunotec K.K., and the Euro for Boulder Diagnostics Europe GmbH. Revenue and expenses of foreign operations are translated into U.S. Dollars at the average rates of exchange during the year. Assets and liabilities of foreign operations are translated into U.S. Dollars at year-end rates. The Company reflects resulting translation gains or losses in accumulated other comprehensive income, which is a component of shareholders' equity. The Company does not record tax provisions or benefits for the net changes in foreign currency translation adjustments, as the Company intends to permanently reinvest undistributed earnings in its foreign subsidiaries.

Realized and unrealized foreign currency transaction gains or losses, arising from exchange rate fluctuations on balances denominated in currencies other than the functional currencies, are included in "Other income (expense)" in the consolidated statements of operations.

Concentration of risks

The Company derives product revenue from the sale of its T-SPOT.TB diagnostic test kits and related accessories to a broad range of customers including: hospitals, public health departments, commercial testing laboratories, importers and distributors. Importers and distributors sell to third parties including end-user customers in specific territories.

In the year ended December 31, 2014, the Company had two product customers that represented more than 10% of the Company's annual revenue. The Company's Chinese distributor, Shanghai Fosun Long March Medical Science Co. Ltd., or Fosun, represented 17% of annual revenue and the Company's Japanese importer, Riken Genesis Co., Ltd. represented 14% of annual revenue. The loss of either of these product customers could have a material impact on the Company's operating results.

In October 2013, the Company issued a convertible promissory note in the amount of \$5.0 million to Fosun Industrial Co., Ltd., (the Fosun Note). The Fosun Note paid interest at 8% per annum. In connection with the Company's IPO in November 2013, the Fosun Note and interest of approximately \$50,000 converted into 467,551 of the Company's ordinary shares at a price per share which reflected a 10% discount to the IPO offering price of \$12.00 per share. Upon conversion of the Fosun Note to ordinary shares, the derivative liability terminated. In connection with the IPO the Company marked the embedded derivative to market and recorded a \$561,000 loss on the change in the fair value of the instrument.

Cash and cash equivalents

The Company maintains its available cash balances in cash, money market funds primarily invested in U.S. government securities, and bank savings accounts in the United States, United Kingdom, Germany, and Japan. The Company maintains deposits in government insured financial institutions in excess of government insured limits. Management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held.

Restricted cash

As of December 31, 2014 and 2013, U.S. bank balances totaling \$312,000 and \$399,000, respectively, were pledged as security for the Company's U.S. office and laboratory space operating leases.

As of December 31, 2014 and 2013, the Company had restricted cash of less than \$100,000 pledged as collateral for procurement cards issued by a U.S. commercial bank.

Accounts receivable

Accounts receivable are primarily amounts due from hospitals, public health departments, commercial testing laboratories, distributors and universities in addition to third party payors such as commercial insurance companies and government programs (Medicare and Medicaid).

Accounts receivable are reported net of an allowance for uncollectible accounts. The process of estimating the collection of accounts receivable involves significant assumptions and judgments. Specifically, the accounts receivable allowance is based on management's analysis of current and past due accounts, collection experience and other relevant information. The Company's provision for uncollectible accounts is recorded as a bad debt expense and included in general and administrative expenses. Although the Company believes amounts provided are adequate, the ultimate amounts of uncollectible accounts receivable could be in excess of the amounts provided.

Inventory

Inventory consists of finished goods and raw materials. The Company does not maintain work in progress balances as the nature of the manufacturing process does not allow for test kits to be left in a partially manufactured state. Inventory is removed at cost. Inventory is stated at the lower of cost or market. Cost is determined by the actual cost of components by batch plus estimated labor and overhead costs per unit. Market value is based on an estimated selling price less any costs expected to be incurred to completion and sale. The Company reviews the components of its inventory on a periodic basis for excess, obsolete or impaired inventory, and records a reserve for the identified items. At December 31, 2014 and 2013, the Company determined no inventory reserve was required.

Property and equipment

Property and equipment are stated at cost. Property and equipment includes specialized shipping containers provided to customers, in the United States, for transporting samples to its laboratory for testing. Property and equipment financed under capital leases are initially recorded at the present value of minimum lease payments at the inception of the lease.

Depreciation is calculated using the straight-line method over the estimated useful lives of the assets. Property and equipment under capital leases and leasehold improvements are amortized using the straight-line method over the shorter of the lease term or estimated useful life of the asset. Depreciable lives range from three to ten years for laboratory equipment, office equipment and furniture and fixtures and three years for software and specialized shipping containers.

Revenue recognition

The Company derives product revenue from the sale of its T-SPOT.*TB* diagnostic test kits and related accessories to a broad range of customers including hospitals, public health departments, commercial testing laboratories, importers and distributors.

Product revenue is generally paid directly by the customer and is recognized on an accrual basis when the following revenue recognition criteria are met: (1) persuasive evidence that an arrangement exists; (2) the product has been shipped or delivered in accordance with the shipping terms of the arrangement; (3) the price is fixed or determinable and known at time of shipment; and (4) collectability is reasonably assured.

For products sold in Japan, the price currently only becomes determinable upon the wholesaler dispatching kits to satisfy a firm order from its customer and, as a result, this is when the Company recognizes revenue for such sales.

No product return rights are extended to customers of the Company.

The Company derives service revenue from its diagnostic laboratories in the United States and in the United Kingdom where the Company performs its T-SPOT.*TB* test on samples sent by customers to its laboratory facilities.

Service revenue in the United Kingdom and revenue from direct bill customers in the United States are recognized on an accrual basis when the following revenue recognition criteria are met: (1) persuasive evidence that an arrangement exists; (2) when the diagnostic result has been delivered; (3) the price is fixed or determinable; and (4) collectability is reasonably assured. This service revenue is referred to as "direct-bill" sales because the Company receives payment directly from the ordering entity.

In the United States, the Company also generates revenue from payments that are received from a variety of third-party payors, including government programs (Medicare and Medicaid) and commercial insurance companies, each with different billing requirements. Revenue from tests paid by third-party payors is recognized on an accrual basis based on the Company's historical collection experience.

Taxes assessed by governmental authorities on revenue, including sales and value added taxes, are recorded on a net basis (excluded from revenue) in the consolidated statements of operations.

Cost of revenue: cost of product and cost of service

Cost of product revenue consists primarily of costs incurred in the production process, including costs of raw materials and components, assembly labor and overhead, quality costs, royalties paid under licensing agreements, the U.S. medical device excise tax and packaging and delivery costs.

Cost of service revenue consists primarily of costs incurred in the operation of the Company's diagnostic laboratories including labor and overhead, kit costs, quality costs, consumables used in the testing process and packaging and delivery costs.

Shipping and handling

The Company does not normally bill its service customers for shipping and handling charges. Charges relating to inbound and outbound freight costs are incurred by the Company and recorded within cost of service.

The Company generally bills product customers for shipping and handling and records the customer payments as product revenue. The associated costs are recorded as cost of product sold.

Impairment of long-lived assets

The Company evaluates its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may be impaired, and assesses their recoverability based upon anticipated future cash flows. If changes in circumstances lead the Company to believe that any of its long-lived assets may be impaired, the Company will (a) evaluate the extent to which the remaining book value of the asset is recoverable by comparing the future undiscounted cash flows estimated to be associated with the asset to the asset's carrying amount and (b) write-down the carrying amount to market value to the extent necessary. There has been no impairment of long-lived assets to date.

Business combinations

For acquisitions meeting the definition of a business combination, the Company allocates the purchase price, including any contingent consideration, to the assets acquired and the liabilities assumed at their estimated fair values as of the date of the acquisition with any excess of the purchase price paid over the estimated fair value of net assets acquired recorded as goodwill. The fair value of the assets acquired and liabilities assumed is typically determined by using either estimates of replacement costs or discounted cash flow valuation methods.

When determining the fair value of tangible assets acquired, the Company estimates the cost using the most appropriate valuation method with assistance from independent third party specialists. When determining the fair value of intangible assets acquired, the Company uses judgment to estimate the applicable discount rate, growth rates and the timing and amount of future cash flows. The fair value of assets acquired and liabilities assumed is typically determined by management using the assistance of independent third party specialists. The assumptions used in calculating the fair value of tangible and intangible assets represent the Company's best estimates. If factors change and the Company were to use different assumptions, valuations of tangible and intangible assets and the resulting goodwill balance related to the business combination could be materially different.

The terms of the purchase agreement with Boulder included contingent purchase price consideration consisting of future potential milestone payments totaling up to \$6.1 million at any time on or prior to July 31, 2024. The milestone payments consist of completion of studies related to acquired technologies, development of diagnostic test kits, patient enrollment in an Institutional Review Board approved study, issuance of patents, and approvals or clearances by the U.S. Food and Drug Administration. The fair value of future potential milestone payments was determined based upon a probability weighted analysis of expected future milestone payments to be made to the seller. This analysis includes significant management judgments related to the probabilities of success assigned to the milestones and to the discount rate utilized in the calculations.

Goodwill and indefinite-lived intangible assets

Goodwill

Goodwill is not amortized but is reviewed for impairment at least annually, or when events or changes in the business environment indicate that all, or a portion, of the carrying value of the reporting unit may no longer be recoverable, using the two-step impairment review. Under this method, the Company compares the fair value of the goodwill to its carrying value. If the fair value is less than the carrying amount, a more detailed analysis is performed to determine if goodwill is impaired. An impairment loss, if any, is measured as the excess of the carrying value of goodwill over the fair value of goodwill. The Company also has the option to first assess qualitative factors to determine whether the existence of events or circumstances leads it to determine that it is more likely than not (that is, a likelihood of more than 50%) that goodwill is impaired. If the Company chooses to first assess qualitative factors and it is determined that it is not more likely than not goodwill is impaired, it is not required to take further action to test for impairment. The Company also has the option to bypass the qualitative assessment and perform only the quantitative impairment test, which it may choose to do in some periods but not in others.

Indefinite-lived intangible assets

The Company's indefinite-lived intangible assets consist of acquired in-process research and development ("IPR&D"), related to the Company's business combination with Boulder, which were recorded at fair value on the acquisition date. IPR&D intangible assets are considered indefinite-lived intangible assets until completion or abandonment of the associated research and development efforts. IPR&D is not amortized but is reviewed for impairment at least annually, or when events or changes in the business environment indicate the carrying value may be impaired. If the fair value of the intangible asset is less than the carrying amount, the Company performs a quantitative test to determine the fair value. The impairment loss, if any, is measured as the excess of the carrying value of the intangible asset over its fair value. The Company also has the option to first assess qualitative factors to determine whether the existence of events or circumstances leads it to determine that it is more likely than not (that is, a likelihood of more than 50%) that its indefinite-lived intangible asset is impaired. If the Company chooses to first assess qualitative factors and it is determined that it is not more likely than not its indefinite-lived intangible asset is impaired, it is not required to take further action to test for impairment. The Company also has the option to bypass the qualitative assessment and perform only the quantitative impairment test, which it may choose to do in some periods but not in others.

The determinations as to whether, and, if so, the extent to which, acquired IPR&D become impaired are highly judgmental and based on significant assumptions regarding the projected future financial condition and operating results, changes in the manner of the use and development of the acquired assets, the Company's overall business strategy, and regulatory, market and economic environment and trends.

Definite-lived intangible assets

Intangible assets include technology licenses which are capitalized and amortized over estimated useful lives (generally in the range of five to ten years) using the straight-line method. On an ongoing basis, the Company assesses the recoverability of its intangible assets by determining its ability to generate undiscounted future cash flows sufficient to recover the unamortized balances over the remaining useful lives. Intangible assets determined to be unrecoverable are expensed in the period in which the determination is made.

Derivative financial instruments

The Company does not use derivative instruments to hedge exposures to cash flow, market, interest rate or foreign currency risks.

The Company reviews the terms of the shares and warrants it issues and its convertible promissory notes to determine whether there are embedded derivative instruments, including embedded conversion options, which are required to be bifurcated and accounted for separately as derivative financial instruments. In circumstances where the host instrument contains more than one embedded derivative instrument, including the conversion option, that is required to be bifurcated, the bifurcated derivative instruments are accounted for as a single, compound derivative instrument.

Bifurcated embedded derivatives are initially recorded at fair value and are then revalued at each reporting date with changes in the fair value reported as other income or expense. When equity instruments contain embedded derivative instruments that are to be bifurcated and accounted for as liabilities, the total proceeds received are first allocated to the fair value of all the bifurcated derivative instruments. The remaining proceeds, if any, are then allocated to the host instruments themselves, usually resulting in those instruments being recorded at a discount from their face value.

Fair value of financial instruments

The Company measures certain financial assets and liabilities at fair value based on the price that would be received for an asset or paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants. As of December 31, 2014 and 2013, the Company's financial instruments consist of cash and cash equivalents, accounts receivable, prepaid expenses, and other accounts payable, accrued liabilities, and loans payable. As of December 31, 2013, the Company's financial instruments also included ordinary share warrants. See Note 2 "Fair value measurement," to the consolidated financial statements for further information on the fair value of the Company's financial instruments.

Research and development expenses

Research and development expenses include all costs associated with the development of the Company's T-SPOT technology platform and potential future products including new diagnostic tests that utilize the T-SPOT technology platform and are charged to expense as incurred. In addition, with the acquisition of Boulder in the third quarter of 2014, the Company has expanded its research efforts to include assays for Lyme disease and gout and an assay to inform decisions regarding biologic therapies. Research and development expenses include direct costs and an allocation of indirect costs, including amortization, depreciation, rent, supplies, insurance, and repairs and maintenance.

Restructuring Charges

For restructuring plans meeting all of the applicable criteria of ASC 420, *Exit or Disposal Cost Obligations*, one time termination benefits will be recognized if no future service is required of former employees. Costs associated with the termination of contracts before the end of their term, where costs will continue to be incurred without economic benefit to the entity, will be recognized as liabilities and initially measured at fair value on the date the contract is terminated or when the Company is no longer using the rights conveyed under the contract. Liabilities for other costs associated with restructuring plans will be recognized in the period they were incurred (generally upon receipt of the goods or services). Restructuring charges will be included in the appropriate operating expense category in the Company's consolidated statements of operations.

Share-based compensation

The Company accounts for share-based compensation arrangements with employees, officers and directors by recognizing compensation expense based on the grant date fair value of share-based transactions in the consolidated financial statements.

Share-based compensation for options is based on the fair value of the underlying option calculated using the Black-Scholes option-pricing model on the date of grant for share options and recognized as expense on a straight-line basis over the requisite service period. Determining the appropriate fair value model and related assumptions requires judgment, including estimating share price volatility, expected term and forfeiture rates. The expected volatility rates are estimated based on the actual volatility of comparable public companies over a historical period equal in length to the expected term. The expected terms represent the average time that options are expected to be outstanding based on the midpoint between the vesting date and the end of the contractual term of the award. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The Company has not paid dividends and does not anticipate paying cash dividends in the foreseeable future and, accordingly, uses an expected dividend yield of zero. The risk-free interest rate is based on the rate of U.S. Treasury securities with maturities consistent with the estimated expected term of the awards.

Beginning in 2014, certain employees have been granted restricted shares. There were no issuances of restricted shares in 2013 or 2012. The fair value of restricted shares is calculated based on the closing sale price of the Company's ordinary shares on the date of issuance. No restricted shares have vested.

The cumulative expense recognized for share-based transactions at each reporting date until the vesting date reflects the extent to which the vesting period has expired and the Company's best estimate of the number of equity instruments that will ultimately vest. The charge or credit for a period represents the movement in cumulative expense recognized as of the beginning and end of that period. No expense is recognized for awards that do not ultimately vest.

Where the terms of an equity award are modified, the minimum expense recognized is the expense as if the terms had not been modified if the original terms of the award are met. An additional expense is recognized for any modification that increases the total fair value of the share-based compensation, or is otherwise beneficial to the employee as measured at the date of modification.

Where a share-based compensation award is cancelled, it is treated as if it had vested on the date of cancellation, and any expense not yet recognized for the award is recognized immediately. However, if a new award is substituted for the cancelled award, and designated as a replacement award on the date it is granted, the cancelled and new awards are treated as if they were a modification of the original award, as described in the previous paragraph.

Upon exercise, share options are redeemed for newly issued ordinary shares.

Income taxes

The Company accounts for income taxes under the asset and liability method, which requires, among other things, that deferred income taxes be provided for temporary differences between the tax basis of the Company's assets and liabilities and its financial statement reported amounts. In addition, deferred tax assets are recorded for the future benefit of utilizing net operating losses and research and development credit carryforwards. A valuation allowance is established when necessary to reduce deferred tax assets to the amount expected to be realized.

The Company adheres to the accounting guidance for uncertainties in income taxes, which prescribes a recognition threshold and measurement process for recording in the financial statements uncertain tax positions taken, or expected to be taken, in a tax return. The Company accrues for the estimated amount of taxes for uncertain tax positions if it is more likely than not that the Company would be required to pay such additional taxes. An uncertain tax position will not be recognized if it has less than a 50% likelihood of being sustained. The Company does not have any accrued interest or penalties associated with any unrecognized tax positions for the years ended December 31, 2014 and 2013.

Ordinary share warrant policy

Warrants to purchase the Company's ordinary shares are classified as equity unless otherwise required. Warrants issued with a down round provision, whereby the exercise price would be adjusted downward in the event that additional ordinary shares of the Company or securities exercisable, convertible or exchangeable for the Company's ordinary shares are issued at a price less than the exercise price, are recorded as a liability and marked to market each reporting period until they are exercised, expire or are otherwise extinguished. Changes in the liability during each reporting period are recorded in other income (expense). The Company has not issued warrants since its IPO in November 2013.

Basic and diluted net loss per ordinary share

Earnings or net loss attributable to ordinary shareholders for the period, after deduction of preferred ordinary share preferences, are allocated between the ordinary shareholders and preferred ordinary shareholders based on their respective rights to receive dividends. Basic and diluted net loss per ordinary share is determined by dividing net loss applicable to ordinary shareholders by the weighted-average number of ordinary shares outstanding during the period. As the Company reports net losses, outstanding share options, warrants and preferred ordinary shares, have not been included in the calculation of diluted net loss attributable to ordinary shareholders per share because to do so would be anti-dilutive. Accordingly, the numerator and the denominator used in computing both basic and diluted net loss per share for each period are the same. Since the Company's participating preferred ordinary shares were not contractually required to share in the Company's losses, in applying the two-class method to compute basic net loss per share, no allocation was made to preferred ordinary shares if a net loss existed. Prior period share and per share amounts have been adjusted to reflect the reverse share split.

Recent accounting pronouncements

In May 2014, the Financial Accounting Standards Board (“FASB”), issued Accounting Standards Update, or ASU, 2014-09, *Revenue from Contracts with Customers*, or ASU 2014-09 which converges the FASB and the International Accounting Standards Board standard on revenue recognition. Under ASU 2014-09, a company should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. This guidance will be effective for the Company for annual and interim periods beginning after December 15, 2016. Early adoption is not permitted. The guidance allows for either “full retrospective” adoption, meaning the standard is applied to all of the periods presented, or “modified retrospective” adoption, meaning the standard is applied only to the most current period presented in the financial statements. The Company is currently evaluating ASU 2014-09 and has not yet determined how it may impact the Company’s financial position or results of operations and related disclosures.

In August 2014, the FASB issued ASU 2014-15, *Presentation of Financial Statements - Going Concern*, or ASU 2014-15. ASU 2014-15 will be effective for fiscal years and interim periods beginning after December 15, 2016 and early application is permitted. ASU 2014-15 requires that management evaluate at each annual and interim reporting period whether there is a substantial doubt about an entity’s ability to continue as a going concern within one year of the date that the financial statements are issued. The Company does not expect that the application of ASU 2014-15 will have an impact on the presentation of its results of operations, financial position or disclosures.

In November 2014, the FASB issued ASU 2014-16, *Derivatives and Hedging*, or ASU 2014-16. The objective of ASU 2014-16 is to eliminate the existing diversity in practice in accounting for hybrid financial instruments issued in the form of a share. A hybrid financial instrument consists of a “host contract” into which one or more derivative terms have been embedded. ASU 2014-16 requires an entity to consider the terms and features of the entire financial instrument, including the embedded derivative features, in order to determine whether the nature of the host contract is more akin to debt or to equity. ASU 2014-16 is effective for fiscal years and interim periods beginning after December 15, 2015, with early adoption permitted. A reporting entity should apply ASU 2014-16 using a modified retrospective approach by recording a cumulative-effect adjustment to equity as of the beginning of the annual period of adoption. Retrospective application is permitted to all relevant prior periods. The Company does not expect that the application of ASU 2014-16 will have an impact on the presentation of its results of operations, financial position or disclosures.

In November 2014, the FASB issued ASU 2014-17, *Business Combinations*, or ASU 2014-17. ASU 2014-17 provides guidance that allows all acquired entities to choose to apply pushdown accounting in their separate financial statements when an acquirer obtains control of them. The new guidance is effective immediately. The Company does not expect that the application of ASU 2014-17 will have an impact on the presentation of its results of operations, financial position or disclosures.

In January 2015, the FASB issued ASU 2015-01, *Income Statement—Extraordinary and Unusual Items*, or ASU 2015-01. ASU 2015-01 eliminates from GAAP the concept of extraordinary items. However, the presentation and disclosure guidance for items that are unusual in nature or occur infrequently will be retained and will be expanded to include items that are both unusual in nature and infrequently occurring. The amendments in ASU 2015-01 are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015. A reporting entity may apply the amendments prospectively. A reporting entity also may apply the amendments retrospectively to all prior periods presented in the financial statements. Early adoption is permitted provided that the guidance is applied from the beginning of the fiscal year of adoption. The Company does not expect that the application of ASU 2015-01 will have an impact on the presentation of its results of operations, financial position or disclosures.

2. Fair value measurement

As a basis for determining the fair value of certain of the Company’s financial instruments, the Company utilizes a three-tier value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level I—Observable inputs such as quoted prices in active markets for identical assets or liabilities.

Level II—Observable inputs, other than Level I prices, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level III—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

[Table Of Contents](#)

This hierarchy requires the Company to use observable market data, when available, and to minimize the use of unobservable inputs when determining fair value. The carrying amount of certain of the Company's financial instruments, including cash, accounts receivable, prepaid expenses and other assets, accounts payable, and accrued liabilities approximate fair value due to their short maturities.

Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the entire fair value measurement requires management to make judgments and consider factors specific to the asset or liability.

The following tables present information about the balances of liabilities measured at fair value on a recurring basis and indicates the fair value hierarchy of the valuation techniques it utilized to determine such fair value. In general, fair values determined by Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities. Fair values determined by Level 2 inputs utilize data points that are observable such as quoted prices, interest rates, and yield curves. Fair values determined by Level 3 inputs are unobservable data points for the asset or liability, and include situations where there is little, if any, market activity for the asset or liability. The Company did not have any financial assets measured at fair value on a recurring basis.

(in thousands)	December 31, 2014	Fair value measurements at December 31, 2014 using		
		Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Liabilities:				
Contingent purchase price consideration	\$ 1,218	\$ —	\$ —	\$ 1,218
Total	\$ 1,218	\$ —	\$ —	\$ 1,218

(in thousands)	December 31, 2013	Fair value measurements at December 31, 2013 using		
		Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Liabilities:				
Ordinary share warrants	\$ 296	\$ —	\$ —	\$ 296
Total	\$ 296	\$ —	\$ —	\$ 296

In May 2013, the Company entered into a loan and security agreement with Square 1 Bank that provided for an initial borrowing of \$6.0 million and, subject to the achievement of certain revenue milestones, the ability to borrow an additional \$1.0 million in January 2014. The Company also received access to a \$5.0 million revolving line of credit. The Company concurrently issued a warrant to purchase up to 15,791 ordinary shares of the Company at an exercise price of \$0.80 per share. Due to the lack of market quotes relating to the Company's ordinary share warrants, the fair value of the warrants was determined using the Black-Scholes model, which is based on Level 3 inputs. In December 2013, following the Company's IPO, the Company repaid the loan in full and canceled the line of credit.

In April 2014, Square 1 Bank converted its warrant and received 15,148 ordinary shares of the Company, in accordance with a formula stated in the warrant agreement. Prior to the warrant conversion, the fair value of the warrant was adjusted to its fair value at the date of exercise of \$318,000, with the loss on change in fair value recorded in the statement of operations. The liability for the warrant on conversion was then reclassified to additional paid-in capital.

On July 31, 2014, the Company acquired substantially all of the assets of Boulder, a privately owned company developing immunology-based assays for autoimmune and inflammatory conditions/diseases. The terms of the purchase agreement included contingent purchase price consideration consisting of future potential milestone payments totaling up to \$6.1 million at any time on or prior to July 31, 2024. The milestone payments consist of completion of studies related to acquired technologies, development of diagnostic test kits, patient enrollment in an Institutional Review Board approved study, issuance of patents, and approvals or clearances by the U.S. Food and Drug Administration. The fair value of future potential milestone payments was determined based upon a probability weighted analysis of expected future milestone payments to be made to the seller, which are considered as Level 3 inputs.

[Table Of Contents](#)

The following tables provide a summary of changes in the fair value of the Company's Level 3 financial liabilities for the years ended December 31:

(in thousands)	2014
Balance – beginning	\$ 296
Change in fair value of warrant liability	22
Reclassification of liability to additional paid-in capital upon exercise of warrants	(318)
Contingent purchase price consideration	1,247
Change in fair value of contingent purchase price consideration	72
Foreign currency adjustment	(101)
Balance – ending	<u>\$ 1,218</u>

(in thousands)	2013
Balance – beginning	\$ —
Initial fair value of warrants at issuance in May 2013	17
Change in fair value of warrant liability	279
Reclassification of liability to additional paid-in capital upon exercise of warrants	—
Balance – ending	<u>\$ 296</u>

The change in fair value of the warrant liability is included general and administrative expense in the Company's condensed consolidated statements of operations and the change in fair value of contingent purchase price consideration is included in research and development expense.

3. Accounts receivable

Accounts receivable, net, consisted of the following as of:

(in thousands)	December 31,	
	2014	2013
Accounts receivable	\$ 6,937	\$ 4,919
Less allowance for uncollectible accounts receivable	(114)	(165)
Accounts receivable, net	<u>\$ 6,823</u>	<u>\$ 4,754</u>

Activity for the allowance for uncollectible accounts receivable is as follows:

(in thousands)	December 31,		
	2014	2013	2012
Balance at beginning of period	\$ (165)	\$ (144)	\$ (200)
Provision for bad debt expense	—	(124)	—
Write-off, net of recoveries	51	103	56
Balance at end of period	<u>\$ (114)</u>	<u>\$ (165)</u>	<u>\$ (144)</u>

4. Inventory

Inventory consisted of the following as of:

(in thousands)	December 31,	
	2014	2013
Raw materials	\$ 3,605	\$ 2,866
Finished goods	2,820	2,584
Inventory, net	<u>\$ 6,425</u>	<u>\$ 5,450</u>

[Table Of Contents](#)

5. Property and equipment, net

Property and equipment, net consists of the following as of:

(in thousands)	December 31,	
	2014	2013
Laboratory equipment	\$ 2,815	\$ 2,072
Leasehold improvements	2,869	2,029
Office equipment, furniture and fixtures	2,603	2,025
Software	1,065	692
Specialized shipping containers	1,088	294
Property and equipment	10,440	7,112
Less accumulated depreciation	(5,903)	(4,148)
Property and equipment, net	\$ 4,537	\$ 2,964

For the years ended December 31, 2014, 2013, and 2012, the Company recorded depreciation expense of \$1.8 million, \$1.0 million, and \$0.7 million, respectively. Depreciation expense includes amortization of capital leases.

Depreciable lives range from three to ten years for laboratory equipment, office equipment, leasehold improvements, and furniture and fixtures and three years for software and specialized shipping containers.

For the years ended December 31, 2014 and 2013, there were no material capital leases, disposals or retirements.

6. Intangible assets

The Company's definite-lived intangible assets include in-licensed intellectual property, principally technology licenses. During the year ended December 31, 2012, the Company entered into a new license agreement under which it capitalized \$0.1 million. During the year ended December 31, 2013, the Company capitalized a \$0.2 million fee related to the assignment of certain patents to it by Isis Innovation Limited (Isis) in November 2013. The licenses are being amortized over the estimated remaining useful lives of the underlying license agreements, which range from 3 to 9 years. The weighted-average useful life of the license agreements is 8.3 years. For the years ended December 31, 2014, 2013, and 2012, the Company recorded amortization expense of \$43,000, \$43,000, and \$30,000, respectively. Amortization expense is estimated at \$41,000 for 2015, \$41,000 for 2016, \$41,000 for 2017, \$26,000 for 2018, and \$25,000 for 2019.

Definite-lived intangible assets, originally denominated in GBP, as of December 31, 2014 and 2013 consist of the following:

(in thousands)	December 31,	
	2014	2013
Gross carrying value	\$ 828	\$ 878
Accumulated amortization	(555)	(547)
Other intangible assets, net	\$ 273	\$ 331

On July 31, 2014, the Company acquired substantially all of the assets of Boulder, a privately owned company developing immunology-based assays for autoimmune and inflammatory conditions/diseases. In conjunction with the acquisition, the Company acquired \$2.6 million of indefinite-lived IPR&D and recorded \$55,000 of goodwill. The following table sets forth the changes in the carrying amount of goodwill for the five-month period subsequent to the acquisition, ended December 31, 2014 (in thousands):

Goodwill from Boulder acquisition	\$ 55
Foreign currency adjustment	(5)
Balance at end of period	\$ 50

For more information on the Boulder acquisition, see Note 18 "Acquisition activity".

7. Accrued liabilities

Accrued liabilities consist of the following as of:

(in thousands)	December 31,	
	2014	2013
Employee related expenses	\$ 3,348	\$ 2,766
Royalties	2,458	2,064
Professional services	323	99
Rent	196	366
Inventory	88	293
Accrued initial public offering costs	—	845
Other accrued liabilities	657	503
Total accrued liabilities	\$ 7,070	\$ 6,936

8. Borrowings

In February 2012 the Company entered into a secured credit facility with a commercial bank that provided for borrowings of up to \$3.0 million originally through February 2013 and extended through May 2013. In February 2012 the Company borrowed \$1.5 million under the credit facility. Interest accrued daily on the outstanding balance at the prime rate plus 1.5% per annum, with a minimum of the Daily Adjusting LIBOR rate plus 2.5% per annum. The credit facility was secured by substantially all assets of the Company. The total amount outstanding on the facility as of December 31, 2012 was \$1.5 million. The loan was re-paid in full on May 24, 2013. The Company had no borrowings in 2014.

In connection with this credit facility, the Company issued a warrant to purchase up to 3,682 ordinary shares of the Company at an exercise price of \$0.06705 per ordinary share. The warrant became exercisable immediately upon entering the secured credit facility and was to expire in February 2019. The fair value of the warrant was \$3,000 at the date of grant and was determined by applying the Black-Scholes option pricing model, using the following assumptions:

	Fair value at date of grant	Valuation technique	Assumption	Input range/ value
Warrant liability (\$ in thousands)	\$ 3	Black-Scholes option pricing model	Expected volatility	37.6%
			Estimated fair value of ordinary share	\$ 0.14
			Exercise price	\$ 0.01
			Expected term (in years)	3
			Dividend yield	0.0%
			Risk-free interest rate	0.37%

The warrant was exercised in March 2014, and the Company issued 3,682 ordinary shares and received proceeds of \$257.74.

In February 2012, the Company entered into an unsecured convertible note agreement with existing investors allowing the Company to borrow a total of \$4.0 million. The Company issued unsecured convertible notes (the 2012 Notes) in two separate tranches of \$3.0 million and \$1.0 million in March 2012 and April 2012, respectively. The 2012 Notes matured four months after funding. The 2012 Notes bore interest at 10% per annum and interest was payable upon redemption or conversion.

Concurrently with the issuance of each tranche of the 2012 Notes the Company was obligated to pay the holders of the 2012 Notes a facility fee, payable in F preferred units, which consisted of one F preferred ordinary share and one-third of an ordinary share per unit. The number of F Preferred Units issued was equal to 50% of the nominal amount of each tranche of the 2012 Notes, divided by \$1.622, with no fractional shares issued. 137,922 F preferred ordinary shares and 45,973 ordinary shares were issued in connection with the March 2012 tranche and 45,974 F preferred ordinary shares and 15,324 ordinary shares were issued in connection with the April 2012 tranche. The fair value of the F Preferred Units on the dates of issuance totaled approximately \$2.0 million. The proceeds from the 2012 Notes were allocated to the 2012 Notes and F Preferred Units based on the relative fair value of each on the issuance dates. The F Preferred Units were recorded as a discount to the 2012 Notes carrying value of \$1.3 million to be amortized to interest expense over the term of the 2012 Notes.

[Table Of Contents](#)

The 2012 Notes were (1) automatically convertible upon the consummation of a qualifying equity fundraising into the class of shares to be issued to investors participating in the fundraising at the price per share at which such shares would be offered, (2) automatically convertible upon the consummation of a non-qualifying equity fundraising into either the class of shares to be issued to investors participating in the fundraising at the price per share at which such shares would be offered or F Preferred Units at a price of \$10.876 per unit, as elected by holders of at least 65% of the nominal amount of outstanding notes, or (3) convertible into F Preferred Units at a price of \$10.876 per unit, at the option of the holders of at least 65% of the nominal amount of outstanding notes upon the consummation of a debt fundraising.

The feature which required automatic conversion upon a qualifying or non-qualifying equity fundraising was a redemption feature that met the definition of an embedded derivative and required bifurcation from the 2012 Notes. The derivative was recorded as a liability with a corresponding discount to the 2012 Notes' carrying value at its fair value of \$0.1 million. The discount was amortized to interest expense over the term of the 2012 Notes.

The feature which provided for the optional conversion upon the consummation of a debt fundraising represented a beneficial conversion feature. Because the beneficial conversion feature was contingent upon a future debt fundraising that was not certain to occur, the beneficial conversion feature was not recognized in the Company's financial statements until the contingency was resolved. In June 2012, the Company closed the first tranche of the G preferred ordinary share financing round. Both tranches of the 2012 Notes were converted into a total of 350,923 shares of G preferred ordinary shares. In a conversion of a convertible bond pursuant to the original conversion terms the debt was settled in exchange for equity and no gain or loss was recognized on conversion. At the conversion date the discount on the borrowing was fully amortized. The redemption feature was adjusted to its fair value of zero upon conversion and the liability was reduced to this amount with an offsetting adjustment to interest expense.

In May 2013, the Company entered a loan and security agreement with a commercial bank that provided for an initial borrowing of \$6.0 million and, subject to the achievement of certain revenue milestones, the ability to borrow an additional \$1.0 million in January 2014. The Company also received access to a \$5.0 million revolving line of credit. The Company concurrently issued a warrant to purchase up to 15,791 ordinary shares of the Company at an exercise price of \$0.80 per share. The loan was secured by substantially all assets of the Company. Interest accrued daily on the outstanding balance at the prime rate plus 2.75%, with a minimum 6.0% per annum. The loan agreement contained certain restrictions on the Company, including restrictions on additional indebtedness, dispositions, dividend payments and future loans. The term loan was repaid and the credit facility was cancelled in December 2013, following the Company's IPO. In addition, the bank released the Company from the security interest in its assets. In conjunction with the termination of the term loan and the credit facility, \$142,000 of deferred loan costs were expensed. The warrant became exercisable upon issuance and was to expire in May 2023. The proceeds from the loan were first allocated to the warrant based upon the estimated fair value as of the issuance date, with the residual proceeds allocated to the term loan. This warrant was issued with a down-round provision whereby the exercise price would be adjusted downward in the event that additional ordinary shares or securities exercisable, convertible or exchangeable for the Company's existing ordinary shares were issued at a price less than the exercise price. Therefore, the fair value of this warrant was recorded as a liability in the consolidated balance sheet and was to be marked to market at each reporting period end until it was exercised or expired or was otherwise extinguished.

The fair value of the warrant was recorded as a liability upon issuance with a corresponding discount on the borrowing of \$17,000 to be amortized to interest expense over the term of the loan. The estimated fair value of the warrants at December 31, 2013 was \$296,000. The change in the estimated fair value of the warrants during the period ended December 31, 2013 was recorded as a component of other income (expense) in the consolidated statement of operations. The fair value was derived by applying the following assumptions:

	Fair value at December 31, 2013	Valuation technique	Assumption	Input range/ value
Warrant liability (\$ in thousands)	\$ 296	Black-Scholes option pricing model	Expected volatility	48.6%
			Estimated fair value of ordinary share	\$ 19.38
			Exercise price	\$ 0.80
			Expected term (in years)	9.4
			Dividend yield	0%
			Risk-free interest rate	2.64%

In April 2014, the holder of the warrant to purchase 15,791 of the Company's ordinary shares elected to exercise the warrant through a cashless conversion, as defined in the warrant agreement. As a result, in April 2014 the Company issued 15,148 ordinary shares in full settlement of the warrant.

[Table Of Contents](#)

In June 2013, in conjunction with the lease for approximately 14,500 square feet of office space in Marlborough, Massachusetts, the Company received a payment of \$581,640 from the landlord, representing approximately 80% of the cost to build-out the facility. In accordance with Financial Accounting Standards Board, Accounting Standards Codification 840, *Leases*, this reimbursement was recorded as a liability in loans payable and is being amortized over the life of the lease. At December 31, 2014, \$108,000 is included in the balance sheet in current portion of loans payable and \$358,000 is included in long-term portion of loans payable.

In October 2013, the Company issued a convertible promissory note in the amount of \$5.0 million to Fosun Industrial Co., Ltd., (the "Fosun Note"). The Fosun Note paid interest at 8% per annum.

In the event of an IPO, the Fosun Note principal and accrued interest were to automatically convert to ordinary shares at a 10% discount to the IPO offering price. Fosun also had an option to elect, prior to July 1, 2014, to require the Company to create and then convert the Fosun Note to H preferred ordinary shares or pay in full all principal and interest outstanding on or before July 1, 2016. In the event of an IPO, the shares were to be subjected to restrictions prohibiting sale or transfer of more than one-third of the shares each year for the first three years following the offering.

The feature which required automatic conversion upon an IPO was a redemption feature that met the definition of an embedded derivative requiring bifurcation from the Fosun Note. The Company determined there was no initial fair market value of the liability.

In connection with the Company's IPO in November 2013, the Fosun Note and interest of approximately \$50,000 converted into 467,551 of the Company's ordinary shares at a price per share which reflected a 10% discount to the IPO offering price of \$12.00 per share. Upon conversion of the Fosun Note to ordinary shares, the derivative liability terminated. In connection with the IPO the Company marked the embedded derivative to market and recorded a \$561,000 loss on the change in the fair value of the instrument.

The Company has restricted cash in the amount of \$80,000 pledged as collateral for procurement cards issued by a commercial bank.

9. Share capital

As of December 31, 2014, the Company had 17,614,650 ordinary shares outstanding. In addition, there were a total of 1,877,142 options and a total of 275,500 restricted shares outstanding as of December 31, 2014.

a. Preferred ordinary shares

Just prior to the Company's IPO in November 2013, all preferred ordinary shares were converted to ordinary shares on a one for one basis.

The following is a summary of the Company's preferred ordinary shares as of December 31, 2012:

	Preferred ordinary shares authorized	Preferred ordinary shares issued and outstanding
A preferred ordinary	134,708	134,706
B preferred ordinary	53,992	53,992
D preferred ordinary	520,275	487,222
E preferred ordinary	4,772,557	2,547,496
F preferred ordinary	2,982,848	2,574,575
G preferred ordinary	3,728,560	1,503,330
	<u>12,192,940</u>	<u>7,301,321</u>

In February 2011 the Company issued 306,499 ordinary shares and 919,498 F preferred ordinary shares for consideration of \$10 million cash in the third and final tranche of the F preferred ordinary share financing round.

The Company issued 137,922 F preferred ordinary shares and 45,973 ordinary shares in March 2012 and 45,974 F preferred ordinary shares and 15,324 ordinary shares in April 2012 in the form of F Preferred Units as a financing fee for the Company's \$4 million issuance of the 2012 Notes.

In June 2012, the Company issued 1,495,464 G preferred ordinary shares for consideration of \$17 million in the first tranche of the G preferred ordinary share financing round. The Company issued an additional 7,882 G preferred ordinary shares in June 2012 as payment of interest on the 2012 Notes.

On December 31, 2012, the Company held \$8.1 million in cash received from investors related to the closing of the second and final tranche of the G preferred ordinary share financing round, which was recorded in shareholders' equity. On January 4, 2013, the remaining cash was received from investors and the Company issued 966,417 G preferred ordinary shares to complete the second and final tranche of the G preferred ordinary share financing, raising a total of \$11.0 million.

[Table Of Contents](#)

The rights, preferences and privileges of the Company's A preferred ordinary shares, B preferred ordinary shares, D preferred ordinary shares, E preferred ordinary shares, F preferred ordinary shares and G preferred ordinary shares (collectively, the preferred ordinary shares) were as follows:

Voting and consent rights—The preferred ordinary shares in issue ranked *pari passu* with regards to voting rights. Holders of preferred ordinary shares were entitled to vote on all matters and were entitled to the number of votes equal to the number of ordinary shares into which each preferred ordinary share was then convertible. The consent of the holders of at least 60% of the E, F, and G preferred ordinary shares outstanding (taken together as a single class) was required for certain corporate actions including a deemed liquidation event, sale of all or a substantial portion of the Company's assets or the creation of any debt of the Company in excess of \$2,000,000. The approval of the holders of G preferred ordinary shares was required for any amendment or change to the Company's articles of association that would be disproportionately adverse to the holders of G preferred ordinary shares and not similarly adverse to the rights of the holders of the other preferred ordinary shares and for the creation of any security convertible into a security having rights, preferences or privileges senior to the G preferred ordinary shares.

Liquidation rights—Upon the liquidation of the Company, including certain transactions deemed to be a liquidation, the holders of G preferred ordinary shares and, as a separate class, the holders of F preferred ordinary shares had a liquidation preference to all other holders of preferred ordinary shares and ordinary shares, in an amount equal to, in the case of the G preferred ordinary shares, 1.25 times the original issue price of \$11.399 per share, and, in the case of the F preferred ordinary shares, 1.50 times the original issue price of \$8.153 per share. The liquidation preference for each of the holders of the G preferred ordinary shares and the F preferred ordinary shares was limited to 50% of the assets or sale amount available for distribution. In the event that the assets or sale amount was insufficient to make such distributions to the holders of G preferred ordinary shares and F preferred ordinary shares separately, then the holders of G preferred ordinary shares and F preferred ordinary shares would have participated, within their own classes, pro rata to their respective shareholdings of G preferred ordinary shares and F preferred ordinary shares, respectively. In the event that 50% of the assets or sale amount available for distribution was sufficient to satisfy one but not the other of the G preferred ordinary share preference and the F preferred ordinary share preference, separately, then any undistributed amount of assets or sale amount would be distributed to either the holders of G preferred ordinary shares or F preferred ordinary shares, as the case may be.

Subsequent to the payments of the liquidation preferences of the G preferred ordinary shares and the F preferred ordinary shares, each holder of E preferred ordinary shares would receive an amount equal to the aggregate amount paid by such holder for such shares, which was \$17.54 for the shares acquired in the first tranche in October 2007, \$17.54 for the shares acquired in the second tranche in August 2008 and £0.006705 for the shares acquired pursuant to cashless exercise of warrants issued in October 2007.

After the payments of the liquidation preferences to holders of G preferred ordinary shares, F preferred ordinary shares and E preferred ordinary shares in full, the remaining assets or sale amount would generally be paid, depending on the amount available for distribution, to holders of all shares based on their respective preferences or, if no preferences are applicable, to all holders on an as-converted basis.

Transfer restrictions—The preferred ordinary shares could have been transferred to any person with the prior consent in writing of holders of shares entitled to cast 90% of the votes exercisable at a general meeting of the Company. The preferred ordinary shares could have been transferred at any time, without prior consent, to certain parties including, where the shares were held by individual members, to certain privileged relations and family trusts; where the shares were held by a company, to a member of the same group as such company; where the shares were held by an investment manager, to a participant or partner in or member of an investment fund which is managed by such investment manager, an investment fund whose business is managed by the investment manager, any other investment manager who manages the business of the investment fund in respect of which the shares are held, or any other person if required by a regulatory authority; where the shares were held by an investment fund, to a participant or partner in or member of such investment fund, any other investment fund whose business is managed by the same investment manager, or the investment manager who manages the business of the investment fund; where the shares were held by trustees under an employee trust, to the new trustees of that employee trust on any change of trustees or to any beneficiary of that employee trust.

Anti-dilution rights—In the event of a relevant issue of securities at a price which, in the case of the G preferred ordinary shares, was less than the original issue price of \$11.399 per share, the Company would have been required to issue to each holder of G preferred ordinary shares such number of ordinary shares as would result in such holder of G preferred ordinary shares holding such number of shares as would be held if the aggregate original issue price of \$11.399 per share in respect of all G preferred ordinary shares then held by such holder was applied wholly in subscribing for the new shares at the weighted-average subscription price in respect of the relevant issue. In the event of a relevant issuance of securities at a price which, in the case of the F preferred ordinary shares and E preferred ordinary shares, was less than the original issue price of \$8.153 per share, the Company would have been required to issue to each holder of E preferred ordinary shares and each holder of F preferred ordinary shares, with the exception of holders of F preferred ordinary shares who received such shares pursuant to the issuance of F preferred units, such number of ordinary shares as would result in such holders holding such number of shares as would be held if the aggregate original issue price of \$8.153 per share in respect of all shares then held by such holder was applied wholly in subscribing for the new shares at the weighted-average subscription price in respect of the relevant issue. In June 2012, the anti-dilution rights resulted in the issuance of 817,761 ordinary shares to the holders of the E preferred ordinary shares. The transaction did not result in the recognition of a beneficial conversion feature as the effective conversion price of the shares exceeded the fair value of the ordinary shares at the date of issuance. Other than the issuance of share capital the transaction did not have accounting implications. In the event that additional shares had been issued as a result of the anti-dilution rights the Company would have recorded the issuance of share capital and assessed whether a beneficial conversion feature or other accounting implications were present. The anti-dilution rights did not preclude the classification of the shares as permanent equity.

[Table Of Contents](#)

Conversion—Upon a conversion, each preferred ordinary share would automatically be converted to, re-designated as, and ranked *pari passu* with the ordinary shares then in issue immediately prior to and conditional upon a qualified listing on a one-for-one basis. Each preferred ordinary share was convertible into one ordinary share at any time at the holder's request.

The Company classified its convertible preferred ordinary shares as permanent equity, as they did not contain redemption rights or other terms that would require classification outside of permanent equity.

b. Ordinary shares

On November 21, 2013, the registration statement for the Company's IPO was declared effective by the Securities and Exchange Commission. The Company sold 6,164,000 ordinary shares, at an initial public offering price of \$12.00 per share, which included the exercise in full by the underwriters of their option to purchase up to 804,000 additional ordinary shares. Net proceeds from the IPO were approximately \$63.9 million, after deducting underwriting discounts and commissions and estimated offering expenses. Following the Company's IPO, the Company now has one class of ordinary shares authorized. As of December 31, 2014, there were 40,103,528 ordinary shares authorized and 17,614,650 ordinary shares issued and outstanding.

10. Share option and equity incentive plans

The Company has issued share options since 2003, and restricted shares since 2014, to incentivize employees and directors providing services to the Company. The Company currently maintains two equity compensation plans, the Amended and Restated 2008 Stock Incentive Plan and the 2013 Share Incentive Plan (the Plans). With the adoption of the 2013 Share Incentive Plan, the Company is no longer authorized to grant awards under the Amended and Restated 2008 Stock Incentive Plan.

In November 2013, in connection with the Company's IPO, the Company adopted the 2013 Share Incentive Plan (the 2013 Plan) which provides for the grant of share options, restricted shares, RSUs and other share-based awards to employees, officers, directors and consultants of the Company. The 2013 Plan authorizes the Company to grant up to 2,684,563 ordinary shares with such amount automatically increasing annually on each January 1st from January 1, 2015 to January 1, 2023 by 4% of the number of shares outstanding on the close of business of the immediately preceding December 31st, provided that the Board of Directors may limit the increase to a smaller amount or to no increase in any given year. At December 31, 2014, there were 1,589,956 shares available for future issuance under the 2013 Plan.

Under both the 2008 Plan and the 2013 Plan, share options, and only under the 2013 Plan, restricted shares, have been granted to employees, officers and directors who provide services to the Company. Options generally vest based on the grantee's continued service with the Company during a specified period following grant or, in rare instances, based on the achievement of performance or other conditions as determined by the Board of Directors, and expire after ten years. Option awards to employees generally vest monthly over a four year period; however, the vesting percentage remains 0% until the second anniversary of the vesting start date of the employee's first option award under the 2008 Plan and either the second anniversary of the employee's date of hire or the first day of the month following the second anniversary of the employee's date of hire under the 2013 Plan. Restricted shares vest based on the grantees' continued service with the Company during a specified period following grant as follows: 40% on the second anniversary of the grant date; 30% on the third anniversary of the grant date; and 30% on the fourth anniversary of the grant date.

Prior to the Company's IPO in November 2013, the Company engaged a third-party consultant to assist the Board of Directors in the determination of the estimated fair market value of the Company's ordinary shares. The share price was determined by the Board of Directors using contemporaneous valuations. In certain instances, the valuation was delivered after the date the options were granted, but was retrospective to an earlier date specified in the valuation report.

Transactions in the Company's shares completed by independent investors represented the best indication of fair value of the securities. In addition, new rounds of venture capital financing, which reflected the expectations of independent investors with respect to the Company's future performance, usually provided a good indication of the fair value of the ordinary shares. In this case, the fair value of the ordinary shares, was derived based on the price paid by the venture capital investors for the preferred ordinary shares, taking into account the differences in various rights and liquidation preferences between ordinary shares and the preferred ordinary shares. This is also known as the back-solve approach. In cases where there were no transactions or new financings, the use of a discounted cash flow analysis and guideline public firm multiples, adjusted for unique characteristics of the Company, were used as accepted methodologies.

The fair value of the options was estimated at the grant date using the Black-Scholes option pricing model, taking into account the terms and conditions upon which options are granted. The fair value of the options is amortized on a straight-line basis over the requisite service period of the awards. The weighted-average grant date fair value per share relating to share options granted under the Plans during the years ended December 31, 2014, 2013, and 2012 was \$9.32, \$3.04, and \$0.27, respectively. Share-based compensation expense for restricted shares is calculated based on the grant date market price of the shares and is also amortized on a straight-line basis over the requisite service period of the awards.

[Table Of Contents](#)

The fair value of each option granted under the Plans has been calculated on the date of grant using the following assumptions:

	2014	2013	2012
Expected dividend yield (%)	—	—	—
Expected volatility (%)	46.87	47.78	49.43
Risk-free interest rate (%)	1.86	1.38	1.03
Expected life of option (years)	6.19	6.22	6.25
Weighted-average share price (\$)	19.66	5.86	0.60
Weighted-average exercise price (\$)	19.66	4.97	0.60
Model used	Black-Scholes Model	Black-Scholes Model	Black-Scholes Model

Expected dividend yield: The Company has not paid and does not anticipate paying any dividends in the foreseeable future.

Risk-free interest rate: The Company determined the risk-free interest rate by using a weighted-average equivalent to the expected term based on the U.S. Treasury yield curve in effect as of the date of grant.

Expected volatility: As the Company operated as a private company until November 2013, there is not sufficient historical volatility for the expected term of the options. Therefore, the Company used an average share price volatility over a historical period equal in length to the expected term, based on an analysis of reported data for a peer group of comparable companies which were selected based upon industry similarities. The Company intends to continue to use comparable companies in its volatility factor calculation until a sufficient amount of historical information regarding the volatility of its own share price becomes available.

Expected term (in years): Expected term represents the period that the Company's share option grants are expected to be outstanding. As the Company operated as a private company until November 2013, there is not sufficient historical share data to calculate the expected term of the options. Therefore, the Company elected to utilize the "simplified" method to value share option grants. Under this approach, the weighted-average expected life is presumed to be the average of the vesting term and the contractual term of the option.

Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from estimates. The Company estimates forfeitures based on historical termination behavior. For the years ended December 31, 2014, 2013, and 2012, a forfeiture rate of 5% was applied.

The following table illustrates the number of ordinary shares and weighted-average exercise prices (WAEP) of, and movements in, share options during the year:

	Number of ordinary shares	WAEP in \$
Outstanding as of January 1, 2013	1,446,807	\$ 0.36
Granted	312,198	5.12
Exercised	(201,459)	0.12
Forfeited	(198,532)	0.24
Outstanding as of December 31, 2013	<u>1,359,014</u>	1.50
Exercisable as of December 31, 2013	<u>1,320,922</u>	\$ 1.48
Outstanding as of January 1, 2014	1,359,014	\$ 1.50
Granted	633,823	19.66
Exercised	(65,054)	0.22
Forfeited	(50,641)	12.30
Outstanding as of December 31, 2014	<u>1,877,142</u>	7.39
Vested or expected to vest as of December 31, 2014	<u>1,829,020</u>	\$ 7.27
Exercisable as of December 31, 2014	<u>914,704</u>	\$ 2.55

[Table Of Contents](#)

The following table illustrates the number of restricted shares and weighted-average fair value (WAFV) of, and movements in, restricted shares during the year:

	Number of ordinary shares	WAFV in \$
Unvested balance as of January 1, 2014	-	\$ -
Granted	275,500	22.25
Cancelled	-	-
Vested	-	-
Unvested balance as of December 31, 2014	<u>275,500</u>	22.25

As of December 31, 2014, there was \$4.9 million and \$4.9 million of total unrecognized compensation cost related to non-vested share options and restricted shares, respectively, granted under the Plans. That cost for unvested share options and restricted shares is expected to be recognized over a weighted-average period of 2.5 years and 3.2 years, respectively.

A summary of options outstanding and exercisable as of December 31, 2014, follows:

Exercise prices	Total options outstanding		Total options exercisable	
	Number of options	Weighted-average remaining life in years	Number of options	Weighted-average remaining life in years
\$0.00 - \$1.00	1,153,736		814,055	
\$1.01 - \$5.00	42,049		7,901	
\$10.00 - \$15.00	160,721		-	
\$15.01 - \$20.00	159,262		24,258	
\$20.01 - \$25.00	361,374		68,490	
	<u>1,877,142</u>	7.9	<u>914,704</u>	6.9

The aggregate intrinsic value of all share options outstanding under the Plans as of December 31, 2014 and 2013 is \$15.7 million and \$24.8 million, respectively. The aggregate intrinsic value of share options that were fully vested under the Plans as of December 31, 2014 is \$10.8 million.

During the years ended December 31, 2014, 2013, and 2012, current and former employees of the Company exercised a total of 65,054, 201,459, and 9,378 share options, respectively, resulting in total proceeds of \$14,000 during 2014, \$24,000 during 2013 and less than \$1,000 during 2012. The intrinsic value of share options exercised during the years ended December 31, 2014, 2013, and 2012 was \$0.9 million, \$3.9 million, and \$6,000, respectively. In accordance with Company policy, the shares were issued from a pool of shares reserved for issuance under the Plans described above.

A summary of the activity of the Company's unvested share options is as follows:

	Number of shares	Weighted-average grant date fair value
Balance as of December 31, 2013	761,840	\$ 1.43
Granted	633,823	9.32
Vested	(385,042)	2.66
Forfeited	(48,182)	6.06
Balance as of December 31, 2014	<u>962,439</u>	5.92

The total fair value of shares vested for the years ended December 31, 2014, 2013, and 2012 was \$1.0 million, \$42,000, and \$12,000, respectively.

[Table Of Contents](#)

The impact on the Company's results of operations from share-based compensation for the years ended December 31, 2014, 2013, and 2012, was as follows:

(in thousands)	2014		2013		2012	
Cost of revenue	\$	330	\$	5	\$	2
Research and development		87		1		4
Sales and marketing		949		26		18
General and administrative		1,155		108		55
Total share-based compensation	\$	<u>2,521</u>	\$	<u>140</u>	\$	<u>79</u>

For the year ended December 31, 2014, the Company incurred share-based compensation expense related to share options and restricted shares of approximately \$1.6 million and \$0.9 million, respectively. For the years ended December 31, 2013 and 2012, the Company only incurred share-based compensation expense related to share options.

11. Net loss per share

The following table provides a reconciliation of the numerator and denominator used in computing basic and diluted net loss per share:

(\$ in thousands)	Year ended December 31,		
	2014	2013	2012
Numerator:			
Net loss attributable to ordinary shareholders	\$ (22,174)	\$ (8,664)	\$ (14,883)
Denominator:			
Weighted-average ordinary shares outstanding-basic	17,310,148	3,830,837	1,763,728
Dilutive effect of ordinary share equivalents resulting from ordinary share options, ordinary share warrants and preferred ordinary shares (as converted)	—	—	—
Weighted-average ordinary shares outstanding-diluted	<u>17,310,148</u>	<u>3,830,837</u>	<u>1,763,728</u>

The following numbers of outstanding ordinary share options, ordinary share warrants, preferred ordinary shares (on an "as converted to ordinary shares" basis) and restricted shares were excluded from the computation of diluted net loss per share for the periods presented because their effect would have been anti-dilutive:

	Year ended December 31,		
	2014	2013	2012
Options to purchase ordinary shares	1,194,612	1,252,790	1,129,657
Ordinary share warrant	—	19,473	3,682
Preferred ordinary shares (as converted)	—	—	7,301,371
Unvested restricted shares	275,500	—	—

12. Related party transactions

In October 2013, the Company issued a convertible promissory note in the amount of \$5.0 million to Fosun Industrial Co., Ltd., (the Fosun Note). The Fosun Note paid interest at 8% per annum. In connection with the Company's IPO in November 2013, the Fosun Note and interest of approximately \$50,000 automatically converted into 467,551 of the Company's ordinary shares at a price per share which reflected a 10% discount to the IPO offering price of \$12.00 per share. The shares are subject to restrictions prohibiting sale or transfer of more than one-third of the shares each year for the first three years following the IPO. The feature which required automatic conversion upon an IPO was a redemption feature that met the definition of an embedded derivative requiring bifurcation from the Fosun Note. The Company determined there was no initial fair market value of the liability. Upon conversion of the Fosun Note to ordinary shares, the derivative liability terminated. In connection with the IPO the Company marked the embedded derivative to market and recorded a \$561,000 loss on the change in the fair value of the instrument.

[Table Of Contents](#)

Revenue on sales to Fosun subsequent to the issuance of the promissory note was \$8.5 million in 2014 and \$1.3 million in 2013. The balance of accounts receivable from Fosun at December 31, 2014 was \$1.4 million and the balance at December 31, 2013 was immaterial.

13. Income taxes

The components of profit (loss) before income taxes are as follows for the years ended December 31:

(in thousands)	2014	2013	2012
Domestic (United Kingdom)	\$ (158)	\$ 4,915	\$ (2,754)
Foreign (United States)	(21,862)	(13,487)	(12,280)
Loss before income taxes	<u>\$ (22,020)</u>	<u>\$ (8,572)</u>	<u>\$ (15,034)</u>

The components for the income tax expense (benefit) are as follows for the years ended December 31:

(in thousands)	2014	2013	2012
Current:			
Federal	\$ —	\$ —	\$ —
UK	—	—	(173)
Japan	119	47	—
State	35	45	22
Total current provision	154	92	(151)
Deferred:			
Federal	—	—	—
UK	—	—	—
State	—	—	—
Total deferred benefit	—	—	—
	<u>\$ 154</u>	<u>\$ 92</u>	<u>\$ (151)</u>

Deferred income taxes reflect the net tax effect of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes.

The Company's effective income tax rate differs from the statutory domestic (United Kingdom) income tax rate as follows for the years ended December 31:

	2014	2013	2012
Income tax rate	21.5%	23.3%	20.0%
U.K. research and development credit	1.7	—	1.1
Other	(1.2)	(0.6)	(0.3)
Effect of foreign tax rate differential	17.9	16.9	15.9
Valuation allowance	(40.6)	(40.6)	(35.7)
Effective income tax rate	<u>(0.7)%</u>	<u>(1.0)%</u>	<u>1.0%</u>

The Company is headquartered in the United Kingdom and the effective U.K. corporate tax rate for the years ended December 31, 2014, 2013, and 2012 was 21.5%, 23.3%, 20%, respectively. The U.S. federal corporate tax rate was 34% for the years ended December 31, 2014, 2013, and 2012. The Company is subject to taxation in the U.S. and various state, local, and foreign jurisdictions. The Company remains subject to examination by various tax authorities for tax years 2011 through 2014. With a few exceptions, the Company is no longer subject to examinations by tax authorities for the tax years 2010 and prior. However, net operating losses from the tax years 2010 and prior would be subject to examination if and when used in a future tax return to offset taxable income. The Company's policy is to recognize income tax related penalties and interest, if any, in its provision for income taxes and, to the extent applicable, in the corresponding income tax assets and liabilities, including any amounts for uncertain tax positions.

[Table Of Contents](#)

Significant components of the Company's deferred tax assets are as follows for the years ended December 31:

(in thousands)	2014	2013
Deferred tax assets:		
Long term deferred tax assets:		
U.S. federal net operating losses	\$ 24,136	\$ 16,897
State net operating loss (net of federal)	3,001	1,659
U.S. federal research and development credit	110	—
U.K. net operating loss	7,800	7,408
Share options	567	112
Accrued liabilities	97	233
Other	78	127
Short term deferred tax assets:		
Accrued liabilities	—	373
Other assets	—	9
Total deferred tax assets	<u>35,789</u>	<u>26,818</u>
Valuation allowance	<u>(35,361)</u>	<u>(26,413)</u>
Total deferred tax assets	<u>\$ 428</u>	<u>\$ 405</u>
Deferred tax liabilities:		
Long term deferred tax liabilities:		
Other assets	\$ (428)	\$ (405)
Total deferred tax liabilities	<u>\$ (428)</u>	<u>\$ (405)</u>

For the years ended December 31, 2014 and 2013, the Company had United Kingdom Net Operating Losses (U.K. NOLs) of \$39.0 million and \$37.0 million, respectively. U.S. federal net operating loss carryforwards for the years ended December 31, 2014 and 2013 were \$71.9 million and \$49.7 million, respectively. U.S. State net operating loss carryforwards for the years ended December 31, 2014 and 2013 were \$63.6 million and \$45.1 million, respectively. The federal and state NOLs include approximately \$0.8 million of deductions related to the exercise of stock options subsequent to the adoption of ASC 718, "Stock Compensation." This amount represents an excess tax benefit as defined under ASC 718 and has not been included in the gross deferred tax asset reflected for NOLs.

The federal and state net operating loss carryforwards begin to expire in 2027 and 2030, respectively and the U.K. NOLs can be carried forward indefinitely.

For financial reporting purposes, a valuation allowance has been recognized to offset the deferred tax assets related to the carryforwards. The utilization of the loss carryforwards to reduce future income taxes will depend on the Company's ability to generate sufficient taxable income prior to the expiration of the loss carryforwards. To date the Company has incurred significant operating losses. In addition, the maximum annual use of net operating losses and research credit carryforwards is limited in certain situations where changes occur in stock ownership.

The following table reflects the rollforward of the Company's valuation allowance:

(in thousands)	2014	2013	2012
Beginning of year (January 1)	\$ 26,413	\$ 22,929	\$ 17,556
Increase in valuation allowance	8,948	3,484	5,373
End of year (December 31)	<u>\$ 35,361</u>	<u>\$ 26,413</u>	<u>\$ 22,929</u>

The Company reviewed its historical tax filings and tax positions and has determined no material uncertain tax positions exist at December 31, 2014 and 2013. The Company continues to monitor its tax filings and positions.

The Company generates research and development credits in the United Kingdom which are refundable if a current year loss is incurred. In the United Kingdom for the year ended December 31, 2012 the Company was reimbursed \$0.2 million, for research and development tax credits. These were recorded as a reduction against income tax expense. For the year ended December 31, 2014 and 2013, no such amounts were reimbursed for research and development tax credits.

14. Intellectual property—license agreements

The Company entered into three license agreements by which it has secured certain patent rights that are necessary to make, use and sell the T-SPOT.TB test. One of these license agreements, with Isis, was terminated in connection with the assignment by Isis to the Company of certain intellectual property rights in November 2013. The Company has ongoing obligations to make certain payments to Isis while the assigned patents remain in force in certain countries. The Company's existing license agreements related to its T-SPOT.TB test, as well as its previous license from Isis, are generally exclusive in the stated field, cover a worldwide territory, are royalty-bearing and give the Company the right to grant sublicenses. The Company has minimum royalty obligations under each existing license agreement, which continue so long as patents licensed under the agreement remain unexpired. The minimum contractual royalty payments, including ongoing minimum payment obligations to Isis, after December 31, 2014 and 2013 are set forth in the commitments and contingencies table in Note 16 "Commitments and contingencies" to these consolidated financial statements.

The Company incurs royalties under each existing license agreement, has incurred royalties under the Isis license agreement, and will incur continuing payment obligations to Isis that are treated as royalties in these financial statements, based on its product and service revenue. The aggregate royalty expense relating to the three license agreements amounted to \$4.8 million, \$3.7 million, and \$2.4 million for the years ended December 31, 2014, 2013, and 2012, respectively. The Company paid other license-related expenses, including patent prosecution expenses, milestone payments and assignment fees due to these licensors, amounting to \$0.1 million, \$0.3 million, and \$0.1 million for the years ended December 31, 2014, 2013, and 2012, respectively. The aggregate royalty rate paid by the Company in the years ended December 31, 2014, 2013, and 2012, as a percentage of the gross product and service revenue of the Company, was 10%, 10%, and 11%, respectively.

15. Employee benefit plans

In the United States, the Company has adopted a defined contribution plan (the U.S. Plan) which qualifies under Section 401(k) of the Internal Revenue Code. All U.S. employees of the Company who have attained 21 years of age are eligible for participation in the U.S. Plan upon employment. The effective date of the U.S. Plan was January 1, 2008. Under the U.S. Plan, participating employees may defer up to the Internal Revenue Service annual contribution limit. The Company does not match employee contributions.

In the United Kingdom, the Company has adopted a defined contribution plan (the U.K. Plan) which qualifies under the rules established by HM Revenue & Customs. The U.K. Plan allows all U.K. employees to contribute a minimum of 5% of salary with no maximum limit. The contribution is matched by the Company, up to a maximum of 5% of salary. The Company paid to the U.K. Plan \$0.5 million in matching contributions in the year ended December 31, 2014, and \$0.4 million in each of the years ended December 31, 2013 and 2012.

16. Commitments and contingencies

Operating leases

At December 31, 2014, the Company leases facilities under four non-cancelable operating leases, with terms that expire between 2018 and 2021. The Company leases office, storage, laboratory and manufacturing space in Abingdon, U.K., which leases are due to expire on January 31, 2018 (with respect to the storage facility) and June 11, 2019. On March 1, 2013, the Company signed a five year lease for its U.S. corporate headquarters in Marlborough, Massachusetts. During June 2013, the Company moved into this facility and vacated the old facility prior to lease expiration on June 30, 2013. The new lease term runs from June 2013 to October 2018. The Company leases laboratory space in Memphis, Tennessee, which lease is due to expire on December 31, 2021. For property in the United States, the Company has bank balances pledged as security as described in Note 1, "Description of business and significant accounting policies—Restricted cash" to these consolidated financial statements.

Future minimum lease payments required under the non-cancelable operating leases in effect as of December 31, 2014 are as follows:

(in thousands)	December 31, 2014
Year 1	\$ 975
Year 2	982
Year 3	843
Year 4	776
Year 5	261
Thereafter	—
Total minimum lease payments	<u>\$ 3,837</u>

Rent expense is calculated on a straight-line basis over the term of the lease. Rent expense recognized under operating leases totaled \$0.7 million for each of the years ended December 31, 2014, 2013, and 2012, respectively.

[Table Of Contents](#)

Purchase commitments

The Company has license agreements with third parties that provide for minimum royalty, license, and exclusivity payments to be paid by the Company for access to certain technologies. In addition, the Company pays royalties as a percent of revenue as described in Note 14, “Intellectual property—license agreements” to these consolidated financial statements. In addition, the Company has outstanding purchase obligations to its suppliers.

Future minimum payments required under license agreements and supplier purchase obligations in effect as of December 31, 2014 are as follows:

(in thousands)	License agreements	Supplier purchase obligations	Total
Year 1	\$ 1,688	\$ 3,180	\$ 4,868
Year 2	1,688	250	1,938
Year 3	1,688	250	1,938
Year 4	1,688	250	1,938
Year 5	1,676	—	1,676
Thereafter	25	—	25
Total minimum license payments	<u>\$ 8,453</u>	<u>\$ 3,930</u>	<u>\$ 12,383</u>

Legal contingencies

The Company is subject to claims and assessments from time to time in the ordinary course of business. The Company does not believe that any such matters, individually or in the aggregate, will have a material adverse effect on the Company’s business, financial condition, results of operations or cash flows.

Indemnification

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnification. The Company’s exposure under these agreements is unknown because it involves claims that may be made against the Company in the future, but that have not yet been made. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. However, the Company may record charges in the future as a result of these indemnification obligations.

In accordance with its articles of association, the Company has indemnification obligations to its officers and directors for certain events or occurrences, subject to certain limits, while they are serving at the Company’s request in such capacity. There have been no claims to date, and the Company has director and officer insurance that may enable it to recover a portion of any amounts paid for future potential claims.

17. Geographic revenue and long-lived assets distribution

The Company is domiciled in the United Kingdom and operates in three geographies: the United States, Europe and the Rest of the World (ROW), and Asia. Revenue and long-lived assets for the years ended December 31, 2014, 2013, and 2012 are shown in the following table:

(in thousands)	Revenue Year ended December 31,			Long-lived assets Year ended December 31,	
	2014	2013	2012	2014	2013
United States	\$ 22,537	\$ 17,345	\$ 10,366	\$ 3,198	\$ 2,496
United Kingdom	2,971	2,795	2,466	928	360
Europe & ROW (excluding United Kingdom)	4,248	4,362	4,064	259	—
Europe & ROW	7,219	7,157	6,530	1,187	360
Asia	19,749	14,282	3,789	152	108
Total	<u>\$ 49,505</u>	<u>\$ 38,784</u>	<u>\$ 20,685</u>	<u>\$ 4,537</u>	<u>\$ 2,964</u>

China represented approximately 43%, 44%, and 82% of Asia revenue in 2014, 2013, and 2012, respectively. Japan represented approximately 54%, 55%, and 7% of Asia revenue in 2014, 2013, and 2012, respectively.

18. Acquisition activity

During November 2012 the Company entered into an agreement to acquire the assets of another corporation. As part of the process, in December 2012 the Company deposited \$0.3 million in an escrow account with an escrow agent that was recorded as restricted cash on the balance sheet as of December 31, 2012. In January 2013 the Company's agreement to purchase the assets was terminated and, in connection therewith the Company received the \$0.3 million cash held in escrow. In February 2013 the Company received a breakup fee in the amount of \$0.2 million, which was recorded in other income, and authorized expense reimbursements of \$0.3 million, recorded as an offset to the related general and administrative expenses.

On July 31, 2014 ("date of the acquisition"), the Company acquired substantially all of the assets of Boulder, a privately owned company developing immunology-based assays for autoimmune and inflammatory conditions/diseases. The assets acquired primarily relate to assays for Lyme disease and gout and an assay to help select biologics for autoimmune disease based on monitoring and prognosis of drug response that was acquired in conjunction with the Boulder acquisition. As part of the transaction, Boulder transferred to the Company all shares of capital stock in its wholly-owned subsidiary, Boulder Diagnostics Europe GmbH, such that the Company has become the sole owner of Boulder Diagnostics Europe GmbH.

The terms of the purchase agreement provided for an upfront payment of \$1.7 million and contingent purchase price consideration consisting of future potential milestone payments totaling up to \$6.1 million in respect of the Lyme disease and gout assays at any time on or prior to July 31, 2024. The milestone payments consist of up to \$400,000 for the completion of studies related to acquired technologies, up to \$700,000 for the development of diagnostic test kits, \$500,000 for the first patient enrolled in an Institutional Review Board approved study, up to \$1.5 million for the issuance of patents, and up to \$3.0 million for approvals or clearances by the U.S. Food and Drug Administration. The Company has determined that this liability is a Level 3 fair value measurement within the FASB's fair value hierarchy and the fair value has been estimated to be \$1.2 million on the date of acquisition based on significant assumptions, including the probabilities of milestone occurrence, the expected timing of milestone payments, and a discount rate of 15%. Such liability is adjusted to fair value at each reporting date, with the adjustment reflected in general and administrative expenses. See Note 2 "Fair value measurement" for information pertaining to changes in the fair value of this liability.

The acquisition of Boulder was accounted for under the acquisition method of accounting and the purchase price allocation was provisionally prepared during the third quarter of 2014. These provisional amounts have been finalized during the fourth quarter of 2014. Total consideration was (in thousands):

Cash consideration	\$	1,724
Estimated fair value of contingent consideration		1,247
Total consideration transferred	\$	<u>2,971</u>

\$183,200 of the cash consideration has been placed in an escrow account for a period of 24 months as security for any undisclosed liabilities and as indemnification for certain items. The Company paid approximately \$181,000 in transaction costs associated with this transaction, which is included in general and administrative expense in the consolidated statement of operations.

The following table summarizes the purchase price of the Boulder acquisition, the fair value of identified assets acquired and liabilities assumed at the acquisition date (in thousands):

Assets acquired:		
Cash	\$	8
Accounts receivable		15
Inventory		40
Prepaid expenses and other		12
Property and equipment		359
In-process research and development		2,627
Total assets acquired		<u>3,061</u>
Liabilities assumed:		
Accounts payable		(97)
Accrued liabilities		(14)
Other current liabilities		(34)
Total liabilities assumed		<u>(145)</u>
Net assets acquired		2,916
Add: goodwill		55
Total consideration transferred	\$	<u>2,971</u>

[Table Of Contents](#)

On the date of the acquisition the fair value of IPR&D acquired was determined to be \$2.6 million (\$1.8 million for the Lyme disease assay, \$0.5 million for the assay to help select biologics for autoimmune disease based on monitoring and prognosis of drug response that was acquired in conjunction with the Boulder acquisition, and \$0.3 million for the gout assay) using the excess earnings method with significant inputs, including estimates of the timing and cost required for product approval, revenue growth, gross margin, operating expenses and a 15% discount rate, that are not observable. The Company considers the fair value of IPR&D to be a Level 3 fair value asset due to the significant estimates and assumptions used by management in establishing the estimated fair value.

Goodwill and IPR&D are indefinite-lived intangible assets and are not amortized. Rather, they are reviewed for impairment at least annually. There was no evidence of any impairment indicators at December 31, 2014 and there were no impairment charges during the year ended December 31, 2014.

Actual results of operations of Boulder are included in the financial statements from the date of the acquisition, including revenues in the amount of \$42,000 and losses from operations of \$396,000. The functional currency for Boulder in Germany is the Euro.

Pro Forma Information: The unaudited pro forma condensed consolidated statement of operations of the Company, set forth below, gives effect to the Company's acquisition of Boulder, using the acquisition method as if it occurred on January 1, 2013. These amounts are not necessarily indicative of the consolidated results of operations for future years or actual results that would have been realized had the acquisition occurred as of the beginning of each such year:

(in thousands, except share and per share data)	Year Ended December 31,	
	2014	2013
Total revenues	\$ 49,577	\$ 38,923
Net loss	\$ (22,399)	\$ (9,669)
Net loss per share—basic and diluted	\$ (1.29)	\$ (2.52)
Weighted average shares outstanding—basic and diluted	17,310,148	3,830,837

19. Restructuring

During the fourth quarter of 2014, the Company closed the facilities that had been used by Boulder (see Note 18 "Acquisition activity"), terminated four employees, and consolidated the research and development activities that had been performed at those locations to the Company's Abingdon, U.K. and Memphis, Tennessee facilities. As a result of these actions, the Company recorded in research and development expense a restructuring charge of \$182,000. A summary of these charges and payments made to date are included in the below table. Accrued restructuring costs at December 31, 2014 are included in accrued liabilities in the accompanying balance sheet.

(in thousands)	Abandonment of Excess Facilities	Relocation Costs	Severance	Total
Balance at December 31, 2013	\$ —	\$ —	\$ —	\$ —
Costs incurred in 2014	86	70	16	172
Payments	(44)	(42)	(16)	(102)
Balance at December 31, 2014	\$ 42	\$ 28	\$ —	\$ 70

In addition to the items listed above, the Company recorded charges totaling \$10,000 to write-off abandoned equipment.

20. Subsequent events

On January 29, 2015, the Company entered into an Underwriting Agreement with several Underwriters, relating to the Offering of 4,255,319 Shares, at an Offering Price to the public of \$11.75 per Share. The Underwriters agreed to purchase the Shares from the Company pursuant to the Underwriting Agreement at a price of \$11.045 per share. Under the terms of the Underwriting Agreement, the Company granted the Underwriters a 30-day option to purchase up to an additional 638,297 Option Shares at the Offering Price, less underwriting discounts and commissions. On January 30, 2015, the Underwriters exercised their option to purchase the Option Shares in full. The gross proceeds to the Company from the sale of the Shares and the Option Shares were approximately \$57.5 million and the Company received net proceeds of approximately \$53.7 million after deducting underwriting discounts and commissions and estimated aggregate offering expenses payable by the Company. The Offering closed on February 4, 2015.

Effective January 15, 2015, the Remuneration Committee of the Board of Directors approved grants to employees for up to 355,509 share options from the Oxford Immunotec Global PLC 2013 Share Incentive Plan. These grants were issued to employees in the first quarter of 2015.

Oxford Immunotec Global PLC Subsidiaries

Entity	Jurisdiction of Organization
Oxford Immunotec Limited	United Kingdom
Oxford Immunotec Inc.	Delaware
Oxford Diagnostic Laboratories (UK) Limited	United Kingdom
Oxford Immunotec K.K.	Japan
Boulder Diagnostic Europe GmbH	Germany
Oxford Immunotec Asia Limited	Hong Kong
Oxford Immunotec (Shanghai) Medical Device Co. Ltd.	Shanghai, China

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statement (Form S-8 No. 333-192582) pertaining to the Amended and Restated 2008 Stock Incentive Plan of Oxford Immunotec Global PLC, the Registration Statement (Form S-8 No. 333-193730) pertaining to the Oxford Immunotec Global PLC 2013 Share Incentive Plan, and the Registration Statement (Form S-3 No. 333-200571) of our report dated March 5, 2015 with respect to the consolidated financial statements of Oxford Immunotec Global PLC included in this Annual Report (Form 10-K) for the year ended December 31, 2014.

/s/ Ernst & Young LLP

Reading, United Kingdom
March 5, 2015

CERTIFICATION

I, Peter Wrighton-Smith, Ph.D., certify that:

1. I have reviewed this Annual Report on Form 10-K of Oxford Immunotec Global PLC;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period for which this report is being prepared;
 - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 5, 2015

/s/ Peter Wrighton-Smith, Ph.D.

Peter Wrighton-Smith, Ph.D.

Chief Executive Officer and Director

CERTIFICATION

I, Richard M. Altieri, certify that:

1. I have reviewed this Annual Report on Form 10-K of Oxford Immunotec Global PLC;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period for which this report is being prepared;
 - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 5, 2015

/s/ Richard M. Altieri

Richard M. Altieri

Chief Financial Officer

CERTIFICATION

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of Oxford Immunotec Global PLC, a company incorporated in England and Wales (the "Company"), does hereby certify, to such officer's knowledge, that:

The Annual Report for the year ended December 31, 2014 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 5, 2015

/s/ Peter Wrighton-Smith, Ph.D.

Peter Wrighton-Smith, Ph.D.

Chief Executive Officer and Director

Date: March 5, 2015

/s/ Richard M. Altieri

Richard M. Altieri

Chief Financial Officer

This certification is being furnished and not filed, and shall not be incorporated into any document for any purpose, under the Securities Exchange Act of 1934 or the Securities Act of 1933.

